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SOUNDWAVE™

PROFESSIONAL SUITE

Device Fitting Manual

Software Version 1.4
August 2006

HARMONY™
HiResolution® Bionic Ear System

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HiResolution® Sound
HiRes® Sound Processing
Auria® BTE
FireFly® Status Indicator
T-Mic® Microphone
Platinum BTE® Sound Processor
HiFocus® Electrode
HiRes90K® Implantable Cochlear Stimulator (ICS)
CII Bionic Ear® Implantable Cochlear Stimulator (ICS)

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Harmony™ Processor
SoundWave™ Professional Suite
Fidelity™ Sound Processing Feature
IntelliLink™ Implant ID Association
Speech Burst™ Stimulus
PowerCel™ Batteries
PowerPak™ Power Supply

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Definition of Terms

Audio Mixing
Audio Mixing enables the clinician to program input from both the processor microphone and an accessory audio input. Audio Mixing allows the processor microphone to remain active when connected directly to a T-Mic, iConnect, Telecoil, Auxiliary mic, or any battery powered external audio-input, such as an FM system, radio, stereo or MP3 player.

Automatic Gain Control (AGC)
A dual loop gain and compression system. One loop adjusts the gain to soft level input while the second loop attenuates transient loud input. The dual AGC automatically adjusts patient sensitivity for optimal audibility and comfort.

Automatic Pulse Width
An algorithm in SoundWave that automatically adjusts stimulation pattern pulse width during programming.

Auto-T
Auto T refers to the automatic setting of threshold levels during programming. T levels are set at 1/10 M across each electrode.

Bi-directional Telemetry
The ability of the system to send and receive information between the processor and implant, allowing measurement of electrode status (impedance), power requirements and lock status when the device is in operation.

Channel
A channel is an independently controlled circuit. For example, two electrodes that are independently controlled would be two channels. The CII and HiRes90K implants employ 16 independent output circuits (channels) coupled to 16 electrodes along the electrode array.

Charge
The relationship expressed as pulse amplitude x pulse width. The product is referred to as charge.

Clinical Units (CU)
Loudness growth is controlled by pulse amplitude and pulse duration. This relationship may be expressed as pulse amplitude x pulse width. The product is referred to as charge. In SoundWave, clinical units represent constant charge (amplitude x pulse width x k, where k = an arbitrary scaling constant) on a scale of 0-6000 CU.

Clipping Level
The level to which stimulation is limited on a specific electrode, typically only adjusted in cases of non-auditory perception (e.g., facial nerve stimulation or discomfort).

Clinician's Programming Interface (CPI)
Gray box which facilitates communication between the processor and computer.

Compliance
The voltage required by the circuit to deliver a specified amount of current through a resistive load (impedance).

Continuous Interleaved Sampling (CIS)
A coding strategy which incorporates sequential, pulsatile stimulation.

Current Steering
Refer to HiRes Fidelity description.

Disable Electrode
Precludes an electrode from being used in the program, i.e., will not be used for stimulation.

Electrical Dynamic range (EDR)
Audibility range from very soft to comfortably loud established by patients T and M level settings.

Electrode Array
The set of electrodes surgically placed in the cochlea, attached to the ICS.

Electrode Conditioning
Conditioning is a two-step process in which stimulation is applied to the electrodes followed by measurement of the electrode impedances. The aim is to "condition" or breakdown the electro-chemical barrier between the electrode and tissue typically found on unstimulated electrodes (such as at initial stimulation).

Export
The copying of a subset of one or more patient files in the SoundWave database to a file that can be imported into any SoundWave database.

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HiRes Fidelity 120 (for HiRes-S and HiRes-P)

HiRes Fidelity 120 has the potential to choose from 120 unique spectral bands for stimulation, if all 16 electrodes are enabled. In theory, active current steering may deliver added spectral information between adjacent pairs of electrodes through accurately weighted simultaneous stimulation of each electrode in the pair during each processing cycle. The CII and HiRes90K implants employ 16 independent output circuits (channels) coupled to 16 electrodes along the array to create 15 adjacent electrode pairs. Each electrode in the pair defines a frequency boundary for the assigned spectral bands. A spectral band for each electrode pair is chosen from eight available spectral bands during each processing cycle. Therefore, for each stimulation cycle across the entire electrode array, a maximum of 15 spectral bands may be selected for stimulation from a total of 120 spectral bands (8 spectral bands x 15 output channels = 120 spectral bands). All enabled electrodes are stimulated in every processing cycle thereby delivering the captured spectrum in each cycle through the electrode array.

Fidelity 120 is programmable on Harmony and PSP processors.

Filter

Each electrode corresponds to a range of frequencies. The center frequency is displayed on the SoundWave program window for each enabled electrode.

FireFly® Diagnostic Indicator

The FireFly (Auria only)is a diagnostic earhook that allows parents, caregivers, or teachers to assess device status/operation. A light located on the Auria FireFly earhook provides information regarding the communication and functional status of the Auria.

Gain

Amplification (dB) that is added to the output of each frequency range.

Gain Profiles

The Gain Profiles adjust gain according to pre-determined levels. There are five profiles that include: Mid Frequency Emphasis, Mid Frequency De-Emphasis, Flat Emphasis, Linear Decreasing, and Linear Increasing.

Global Tool Adjustment

Arrow buttons allow you to increase/decrease levels (up/down) or move through the array (left/right) Adjustments are made globally when the Global Selection Tool is enabled, and individually when it is disabled.

Global Tool Selection

Allows you to make global changes to M and T levels.

HiRes®

Advanced sound processing strategies that are designed to more accurately represent sound and enhance temporal resolution. The following options are available: HiRes-P, HiRes-S, HiRes-S with Fidelity 120, and HiRes-P with Fidelity 120.

HiResolution®

HiRes® sound processing represents an advanced method for the capturing, composing, detailing, and delivering of sound for hearing with a cochlear implant. HiRes® is only available on the HiResolution Bionic Ear System.

HiRes-P

A HiResolution coding strategy which delivers stimulation simultaneously to two electrodes.

HiRes-S

A HiResolution coding strategy which delivers stimulation to one electrode at a time sequentially.

Impedances

Impedance relates to the ability of the electrode to delivery current stimulation to the surrounding tissue. Impedance is related to electrical resistance.

Implantable cochlear stimulator (ICS)

The electronics package (receiver/stimulator) surgically implanted on the skull base behind the ear.

Initialization

Prepares the processor for programming in SoundWave.

Input Dynamic Range (IDR)

The range of captured acoustic input that is mapped into the patient's electrical dynamic range.

IntelliLink™

Limits stimulation to a particular implant. This is done by reading the unique serial number directly from the implant and associating that number with a particular patient. When this feature is active, programs downloaded to a processor will not stimulate any implant other than the one to which it is associated. This feature provides an important safety measure, and although it can be disabled, we recommend that you take advantage of this proprietary feature.

Light-emitting diode (LED)

Light on PSP and Harmony BTE which illuminates to indicate battery charge status, lock status and microphone status.

Live Speech

This option activates the patient's microphone permitting the capture of sound from the acoustic environment.

Lock

The term lock refers to the successful communication of signals between the external hardware (processor, cable, and headpiece) and the implant across the skin.

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Most Comfortable Level (M)
The level of stimulation (measured in CU) the patient judges as comfortably loud.

Multiple Pulsatile Sampler (MPS)
A coding strategy which presents pulsatile stimulation to a minimum of two electrodes simultaneously.

Neural Response
A neural response is a small change in voltage that occurs when neurons fire in synchrony.

Neural Response Imaging (NRI)
The method by which we can measure responses from the auditory nerve using the HiResolution Bionic Ear System.

PoEM (Power Estimator)
Adjusts RF based on the dynamic input of various listening environments to improve lock stability across listening situations, to compensate for changes in patient skin flap thickness that naturally occur over time, and between various hardware configurations (that is when you swap cables, headpieces or processors).

Power Economy Mode
Power Economy Mode (Harmony only) optimizes (increases) battery life. This option is the default setting displayed during processor initialization.

Program
A saved parameter set which has been adjusted to the acceptance of the implant recipient. Programs are downloaded to the processor.

Program ID
SoundWave automatically assigns a number in sequential order to each program when it is saved. You can hide programs from view, but you cannot delete programs.

Pulse Width (PW)
Pulse width indicates the duration of one phase of the biphasic stimulating waveform.

Pulsatile Stimulation
Acoustic waveform is translated into biphasic electrical pulses to be presented to an electrode.

Radio Frequency (RF)
The carrier frequency used for telemetry (i.e. communication between the implant and processor).

Rate

Channel	Pulses per second per channel. Also called Repetition Rate.
Total	The accumulated pulses per second across the entire array.

Sensitivity
Sensitivity controls the response of the microphone to input intensity. Raising the sensitivity includes more distant sounds, lowering the sensitivity excludes more distant sounds.

Slots
A slot is a position on the processor that is used to store a downloaded program. Sometimes also called program position.

Spectral Band
A spectral band is derived by filtering the input acoustic signal using processing functions and assigned to a discrete address or location along the electrode array for stimulation. Each electrode or electrode pair can be stimulated simultaneously or sequentially.

Speech Bursts
The stimulation used for setting M levels on a group of 3 to 4 electrodes at the same time.

Speech M
Level of stimulation at which a patient perceives speech to be most comfortable.

Threshold Level(s)
The minimum stimulation level (measured in CU) a patient can detect.

Volume
Adjusts M levels via sound processor volume control. The volume range allows you to set the range of the volume control on the processor.

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SOUNDWAVE™

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Patient and Clinician Fitting Equipment

HARMONY™

HiResolution® Bionic Ear System

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Patient Hardware

Internal Components

The Implantable Cochlear Stimulator (ICS) contains the system's electronics. The ICS is surgically placed and secured within the surface of the skull. The HiFocus® electrode array, inserted into the cochlea (typically into scala tympani), is attached to the ICS.

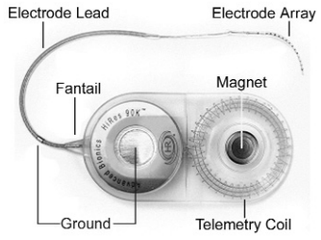

Figure 1. HiRes90K® ICS

Figure 2. CII Bionic Ear® ICS

The HiResolution® Bionic Ear System includes two types of ICSs, the CII Bionic Ear® and the HiRes90K®. While they are different in style, the two are identical in stimulation capability. The ICS consists of various components that contribute to the flexibility, capability, and safety of the HiResolution Bionic Ear. The *custom chip* has the capability to deliver stimulation rates up to 83,000 pulses per second (pps). Sixteen (16) *independent output circuits* (one per electrode) with precision current sources permit varying simultaneous stimulation patterns across different electrodes. *Output capacitors*, one per electrode, are also included to ensure safety of the neural tissues from DC current. The *internal memory chip* can directly store static program parameters within the ICS permitting the broadband transmission of HiResolution sound. The technological headroom of the implant will enable today's cochlear implant recipients to access tomorrow's advances in sound processing through software upgrades.

The ICS contains RF receiver/transmitter coils. An internal magnet aligns the coil in the ICS to the coil in the headpiece to ensure proper communication between the implant and the sound processor during device use. The systems incorporate two separate RF carriers: one for forward telemetry, or sending information from the processor to the implant (49 MHz) and one for the back telemetry, or sending information from the implant to the processor (10.7 MHz). Telemetry is used for measuring impedances, recording the electrically evoked compound action potentials (ECAP) and assessing power requirements. The benefit of having two carrier frequencies is the ability to continually monitor the function of the implanted components and sound processor, even during patient use. The HiResolution Bionic Ear is able to offer alarms and visual alerting mechanisms indicating communication status, program selection and battery status which are monitored during device operation.

The HiResolution Bionic Ear is programmed with HiResolution sound processing using the SoundWave™ Professional Suite software detailed in this manual.

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External Components

Five sound processors (SPs) are currently in use with the HiResolution Bionic Ear System: four behind-the-ear (BTE) style processors, (the Auria® Harmony™ Processor, the HiRes® Auria® Processor, the CII BTE Processor, the Platinum BTE® Processor) and one body-worn processor, the Platinum Sound Processor (PSP).

Harmony and Auria

The Harmony and Auria are ear level sound processors designed for style, comfort and performance.

The Harmony and Auria share the following features:

- Three program slots
- User friendly controls for program selection and volume setting
- Audio earhook options
- Powered by custom rechargeable PowerCel™ batteries
- Available in three base colors; (Dark Sienna Metallic, Beige Metallic and Silver Metallic) along with a selection of color covers and caps to create up to 60 color combinations

The Harmony also offers the following features:

- Ability to support Fidelity 120
- CD quality (16-bit) front-end processing
- Built-in LED to monitor system status
- Built-in telecoil
- Power Economy Mode for increased battery life

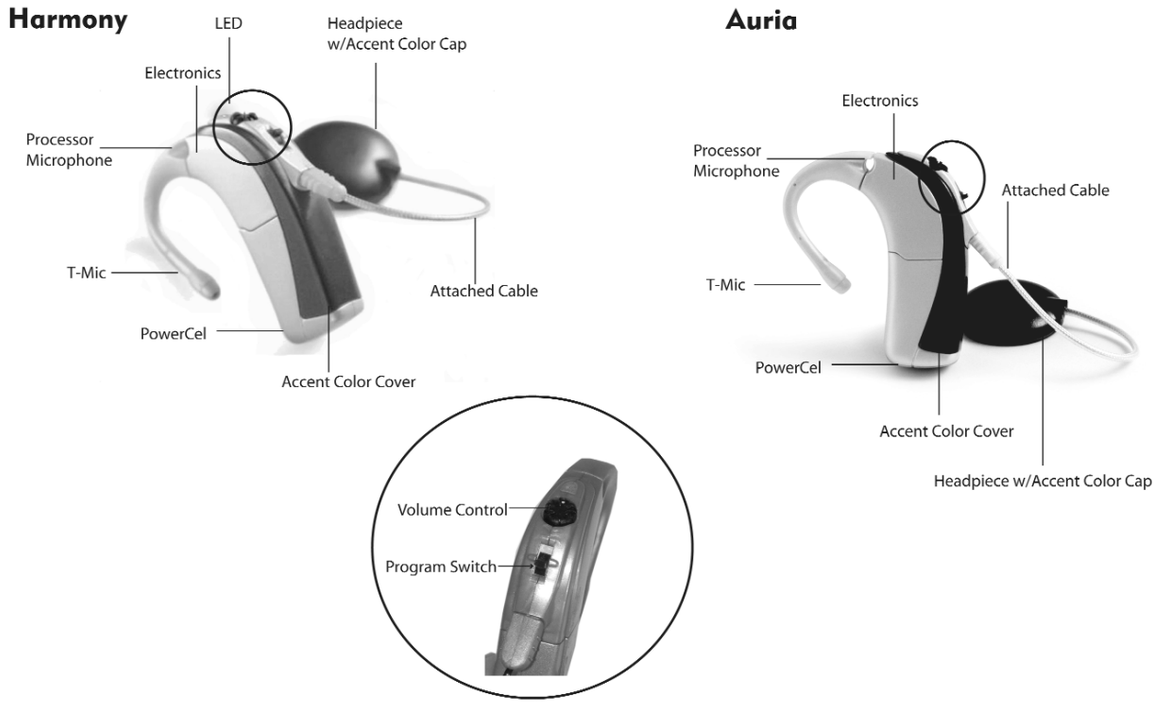

Figure 3: The Harmony and Auria Processors

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Harmony and Auria Headpiece

These headpieces are lightweight, have a low profile and house the transmitting coil that sends sound information to the implant via RF.

Two designs are available. One is concave and includes a 4.25" cable. This design comes standard with the Harmony Processor. The concave headpieces were designed for use with the HiRes 90K® (HR90K) to more comfortably conform to the shape of the implanted device. This shape allows the magnet force to be more evenly distributed over the skin flap minimizing irritation and reducing the likelihood of the headpiece being easily dislodged. The reinforced cable connecting the headpiece to the processor is permanently attached to the headpiece. A two-contact plug connects the headpiece to the processor by a connector located immediately below the program switch. A magnet within the headpiece attracts to the magnet on the implant to align the transmitting and receiving coils. The headpiece was designed to accommodate variable skin flap thickness.

The other headpiece design is "flat" and comes with a 3.5" cable. This design was intended for use with the C-I (1.0 and 1.2) and CII implants. This headpiece can also be used with the Platinum BTE and the CII BTE.

Adjusting Magnet Strength

The magnet within the headpiece is permanent, and the headpiece should not be opened. If required, an additional magnet can be placed in a well (round indented groove) on the underside of the headpiece. HR90K/Auria headpieces are shipped with a plastic filler positioned in the headpiece magnet well and a spare plastic filler with adhesive backing for future use, if needed. To add an additional magnet, first remove the plastic filler from the headpiece well, then place the magnet in the well. Use a single (half or full strength) magnet specifically designed for this purpose and available from Advanced Bionics. To minimize the potential for skin irritation and other problems, only one magnet should be added to the underside of the headpiece. When an additional magnet is no longer needed with the concave headpiece, place a plastic filler into the headpiece well to prevent puckering of the skin flap into the well. Remove the magnet using the Magnet Removal Tool and place a plastic filler back into the headpiece well, adhesive side down. Additional plastic fillers can be obtained by contacting Advanced Bionics Customer Service.

Figure 4: Headpiece Magnet Removal Tool

Warning: The use of extra magnets or other magnets not specifically designed for use with this particular type of headpiece can cause skin irritation and may affect the headpiece tuning, causing lock, intermittency, and/or skin flap issues. If your patient requires an extra magnet, watch for signs of irritation or swelling. After extended use, an extra magnet on the headpiece may no longer be required, and we recommend that you attempt to refit your patient with a reduced strength magnet or without the extra magnet on the headpiece. Please contact Advanced Bionics with any questions regarding headpieces and skin flap health.

Harmony and Auria Microphone

The Harmony and Auria feature a forward facing omnidirectional microphone housed within the processor at the base of the earhook.

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Power Supply Options

PowerCel™

PowerCels power the Harmony or Auria and permit equivalent processing capabilities of a body-worn processor. PowerCel technology is cost effective and environmentally friendly. Average daily operating times vary depending upon the type of BTE and PowerCel as well as across patients due to flap differences.

PowerCels slide onto the processor to activate the device. The tracks, along the PowerCel and processor, direct the PowerCel in place making it easy to use especially for patients with vision or dexterity limitations.

Two power supply options are available for use with the Auria and Harmony:

- PowerCel Slim
- PowerCel Plus

While battery life will vary depending on program settings and patient specific needs, average daily operating times for new batteries used with the Auria are approximately 8 hours with the PowerCel Slim and about 16 hours with the PowerCel Plus and for the Harmony 14 hours with the PowerCel Slim and about 24 hours with the PowerCel Plus.

Figure 5: Auria PowerCel

Auria PowerPak™ (Available for use with the Auria only. Not compatible with the Harmony Processor)

The Auria PowerPak provides the capability to use AA battery. It easily screws open and closed to replace or remove the battery. As with the PowerCel, attaching the PowerPak activates the Auria. Tracks along the PowerPak and Auria guide the PowerPak in place. A latch secures the PowerPak to the Auria. The PowerPak can be clipped to clothing or worn in a pocket or pouch. The cable is available in different lengths (11", 22", and 32"). The PowerPak provides operating times averaging 25 hours with an alkaline battery, When using the PowerPak configuration, the Auria can be worn with an optional huggie to secure the processor to the ear.

Warning: Follow the recommendations of the battery manufacturer; never attempt to charge non-rechargeable batteries.

When in use, the PowerPak should not be carried in any type of carrying case, pouch or pocket, which could obstruct airflow to the PowerPak causing its temperature to rise. In the unlikely event of a PowerPak failure, obstruction of airflow could result in a case temperature increase of up to 20° C (36° F) which could potentially result in a significant burn.

Parents or caretakers of infants and children should periodically check to ensure that the PowerPak has not accidentally moved from its correct placement as a result of normal activities, causing airflow to be obstructed, particularly when unexpected/unusual crying behaviors are noted.

Figure 6: Auria with Huggie and PowerPak

Figure 7: Auria PowerPak

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PowerCel Charger

There are 2 charger designs in use for the PowerCels (Figures 8 and 9). Both designs can charge up to 4 PowerCels, either Slim or Plus, at once. Each charger comes with a power supply and international adapters. A green light illuminates on each charger when powered (plugged in). The chargers are compatible with the PowerCels used for the Harmony, Auria or the previous generation BTEs (CII and Platinum).

A green light located next to the power supply socket lights up when the charger is connected to a power source. This indicates that power is being received by the charger.

The original design of the charger (shown in Figure 8) contains a light for each PowerCel. The light is yellow when the PowerCel charging cycle is in progress and turns off when the PowerCel is fully charged. PowerCels slide on to the charger by aligning the pins and tracks and gently sliding in place. To remove a PowerCel from the charger, depress the charger button and gently lift the PowerCel off the charger. Although you can use the Original PowerCel charger to recharge all PowerCels, we recommend using the redesigned charger (shown in Figure 9) when charging a PowerCel Plus.

Figure 8: Original PowerCel Charger

Figure 9 shows the redesigned charger. There are 2 indicator lights for each PowerCel. When a PowerCel is charging, an amber light located next to the lightening bolt [ ] illuminates. This light will turn off when the PowerCel is fully charged. A red light located next to the exclamation mark [!] illuminates if the charger recognizes any fault with an attached PowerCel, such as when a PowerCel is damaged or the chemistry is depleted (that is, it cannot be recharged anymore). PowerCels are placed on the charger guided by the tracks. To remove, slowly pull the PowerCel off the tracks. The charge cycle is 3-5 hours. PowerCels do not need to be fully depleted before recharging. Patients should be counseled to rotate their PowerCels to prolong their lifespan. The PowerCel charger also comes with a set of power adapters for international use.

Figure 9: Redesigned PowerCel Charger

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Harmony and Auria Operation

Volume Control

Patients use the volume control during normal operation to adjust loudness. The volume control is a rotary dial with a white dot indicating the volume setting. Typically, Most Comfortable Level (M Level) is set during programming in response to Live Speech with the volume set at 12:00. When rotated clockwise, the volume increases (maximum at 5:00). When rotated counter-clockwise, the volume decreases (minimum at 7:00). The maximum and minimum volume is set by the clinician during programming between -100 to +100% of the dynamic range based on individual user needs. Typically patients require < 50% range. The default setting is -50 to +50%. Setting the volume range customizes the volume dial for each patient and prevents accidental increases in loudness above a patient's comfortable range.

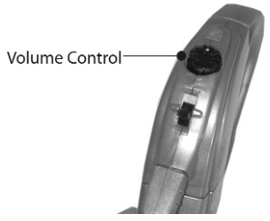

Figure 10: Harmony and Auria Volume Control

Sensitivity

Sensitivity is a program parameter set by the clinician when programming with SoundWave. You will create programs with different levels of sensitivity depending upon individual patient requirements. You will adjust and set sensitivity using the Sensitivity slider on SoundWave's program window. When the sensitivity is set below the default (decrease dB setting), gain is reduced so that closer, high intensity sounds can be heard, such as the patient's own voice or speech from a nearby talker. When the sensitivity is set above the default (increase in dB setting), gain is increased so that softer sounds often at a greater distance from the patient can be heard, but environmental sounds and noise also become more audible. The sensitivity setting is saved with the program and serves as the program default.

Program Switch

The program switch is a three position switch. The following graphic depicts the three program positions. Users select a program by moving the switch in the upward or downward direction.

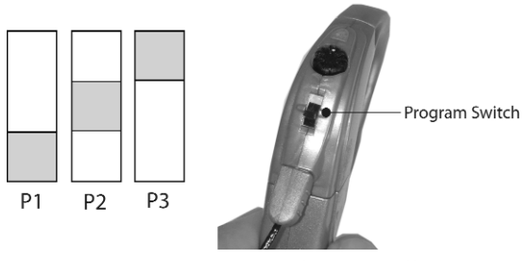

Figure 11: Harmony and Auria Program Switch

On/Off

The processor is turned on and off by connecting or removing the PowerCel or PowerPak (Auria Only). When not using the processor, patients should remove the PowerCel or PowerPak; otherwise, the processor remains on and continues to drain the battery.

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Harmony Tri-color LED

The Harmony Processor is equipped with a built in light emitting diode (LED) status indicator.

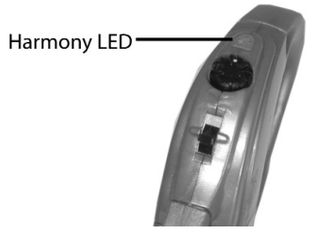

Figure 12: Harmony LED

The LED is a diagnostic light that provides users, parents, caregivers or teachers with information regarding the status of the processor. The LED is located above the volume dial and can be programmed to provide the information that follows.

PowerCel™ Charge Status

When the Harmony Processor is first turned on, the LED lighting sequence will indicate the PowerCel charge status. The blinks of the ORANGE LED mean:

- 4 quick blinks indicate that the PowerCel is fully charged.
- 2-3 quick blinks indicate that the PowerCel is sufficiently charged to power the processor.
- 1 quick blink indicates that the PowerCel charge is nearly depleted (low battery).
- Orange LED doesn't light up at all: Depleted Battery. Replace PowerCel with a charged one.

Lock Status

The term ***lock*** refers to the successful communication between the processor and implant. Following the PowerCel charge status sequence, a RED light will begin to flash approximately once per second until lock is achieved. The light will begin to flash 1-5 seconds after the processor is unable to lock on the implant. Once the headpiece is properly positioned on the patient's head, and information is transmitting to the implant, the flashing will stop.

Microphone/System Status (programmable feature)

When the PowerCel status and lock sequence are complete, microphone and system status can be verified if this feature is enabled for the selected program. A GREEN light will flicker in response to loud sounds presented near the processor microphone. This verifies that the microphone is receiving sound, data is being transmitted to the implant and the Harmony Processor is receiving information back from the implant. The green light is not expected to illuminate continuously during everyday use, especially if the patient is in a quiet environment. For this feature to operate, both the Status LED and the Automatic Gain Control (AGC) must be enabled for the program. Both are enabled by default. If AGC or Status LED are disabled, no light will flicker in response to loud sounds.

NOTE: The Status LED is automatically disabled when the built-in telecoil is enabled. The GREEN light will NOT flicker in response to loud sounds if the built-in telecoil is enabled.

Low Battery and Change Battery Indicator (programmable features)

When the PowerCel is near depletion, a steady ORANGE light will illuminate if this feature is enabled for the selected program indicating that it is time to change the PowerCel. When the PowerCel is depleted to the point that it is unable to support stimulation but not completely depleted, the ORANGE light will blink twice every 3 seconds. Once the battery is fully depleted, no light will emit from the processor and no sound will be transmitted to the implant.

NOTE: This feature is disabled by SoundWave for programs with the built-in telecoil enabled.

IntelliLink™ (Implant ID Indicator)

Should you accidentally attempt to use the wrong processor, a RED light will rapidly flash indicating that the processor is trying to lock with the wrong implant. In this case, no sound will be transmitted to the implant.

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Microphone Test Indicator

When an empty program slot is selected, a steady GREEN light will illuminate indicating that the processor is ready for testing the built-in microphone. Built-in microphone testing can be performed without the need for an amplified speaker. Connect ear/headphones directly into the Direct Connect Cable that is attached to the Direct Connect Earhook and the Harmony Processor, in stand-alone mode powered by a PowerCel.

Processor Error Indicator

In rare instances, the Harmony Processor LED may emit a continuous RED light. This indicates a potential problem with your Harmony Processor. If this should occur, first remove and replace the power source to see if the problem continues.

Table 1: Summary of Harmony Tri-color LED Functionality

Color	Feature	Description	Programmable Feature
Orange	PowerCel Status	When a PowerCel is inserted onto the processor module, the ORANGE LED will blink as follows: • 3 to 4 quick flashes indicates that the PowerCel is fully charged, • 2 quick flashes indicates that the PowerCel is suffciently charged to power the system, • 1 quick flashes indicates that the PowerCel charge is nearly depleted.	No
	Low Battery Indicator	When the PowerCel is near depletion, a steady ORANGE light will illuminate indicating that it is time to change the PowerCel. Once the battery is fully depleted, no light will emit from the processor and no sound will be transmitted to the implant. Replace PowerCel as soon as possible.	Yes
	Change Battery Indicator	When the PowerCel is depleted to the point that it is unable to support stimulation but not completely depleted, the ORANGE light will blink twice every 3 seconds and no sound will be transmitted to the implant.	Yes
Green	Mic/System Status	Flashes in response to loud sounds when AGC is enabled when connected to the CPI or standalone. The Status LED is automatically disabled when the built-in telecoil is enabled. The GREEN light will NOT flicker in response to loud sounds if the built-in telecoil is enabled.	Yes
	Mic Test Mode	Steady green light indicates empty program slot available for mic testing.	No
Red	Lock Status	Blinks at 1 second interval indicating no lock with implant.	No
	IntelliLink™	Rapid blinks (indicates wrong implant is connected)	No
	Error Conditions	Continuous - fully remove and reinsert PowerCel to reset processor.	No

Note: When the Harmony is connected to the CPI, the Lock Status Indicator and Mic/System Status will always be functional indicating No lock (blinking RED) or in response to Sounds (blinking GREEN). When AGC is disabled, the Mic/System Status WILL NOT blink GREEN in response to sound whether in stand-alone (Disconnected from CPI powered by battery) or Fitting Mode (Connected to the CPI).

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Harmony and Auria Audio Earhook Options

Patients have a choice of ear hook options for the Harmony and Auria Processors for ease of listening, comfort and connectivity. Available options include the Auria T-Mic, Auria iConnect, Auria Direct Connect, and the Auria Standard earhook. The Auria FireFly® is also available for the Auria BTE, but is not compatible with the Harmony BTE as the LED is built-in to the Harmony Processor.

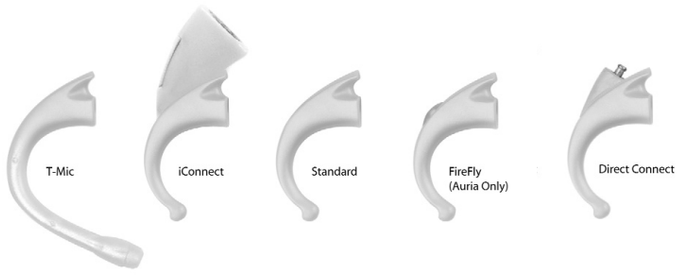

Figure 13: Harmony and Auria Earhook Options

T-Mic® Microphone

The T-Mic microphone is located at the ear canal opening to take advantage of the outer ear's natural sound collecting properties. It is intended to enhance high frequency sounds, signal-to-noise ratio and localization ability. The T-Mic is available in two sizes: standard and small.

- Preferred earhook option for everyday use.
- Enables normal use of telephones, even cellular phones - no switches.
- Enables normal use of headphones and some Bluetooth modules for ALD and consumer electronic connectivity.
- No noise due to electromagnetic interference common to telecoils.

You must download programs with the Audio Mixing ratio set to for Aux input. Typically 100% Aux (T-Mic only) is recommended.

iConnect

The iConnect provides cable free, wireless connection to miniature FM receivers directly at ear level. The iConnect is available in two sizes: standard and small.

- iConnect's cable-free compatibility with the most common advanced miniaturized FM receiver used in schools, the Phonak MicroLink MLxS, makes FM access affordable for parents and schools.
- With a separate power source, the iConnect provides reliable FM reception without compromising the processor's power supply.

Direct Connect

The Direct Connect ear hook enables children and adults to connect to many battery powered auxiliary devices, such as CD/MP3 players, and FM systems. To connect directly to third party auxiliary devices using a standard 3.5 mm stereo jack it is necessary to use both the Direct Connect Cable (available in 11", 24", and 36" lengths) and the Audio Interface Cable (available in one standard length). Remember that in order to use an auxiliary device, you must create and download programs with the Audio Mixing ratios set appropriately (typically 50/50 or 30/70 is preferred). The Direct Connect is available in two sizes: standard and small.

External T-Coil

The T-Coil connects to the Direct Connect earhook option and allows for wireless connection to loop systems (typically found in public facilities) and hearing aid compatible telephones.

NOTE: Harmony also contains a built-in telecoil option that can be enabled during download to the processor.

Standard Earhook

The standard earhook is designed to hold the processor in place on the ear, but does not provide any additional audio option. The standard earhook is available in two sizes: standard and small.

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Auria FireFly® Diagnostic Indicator (Auria only)

The FireFly is a diagnostic earhook that allows parents, caregivers, or teachers to assess device status/operation. A light located on the Auria FireFly earhook provides information regarding the communication and functional status of the Auria.

NOTE: Harmony contains a built in LED diagnostic indicator. The Firefly is not compatible with Harmony.

The following table describes the function of the Firefly and the status being indicated.

Table 2: Auria FireFly Functional Description

Function	Description
Program Selection:	As you switch from one program to the next, the Auria FireFly will flicker either 1-2-3 times depending on the program position to which you are switching. The LED will flash rapidly if a program position is empty. *Note: The LED will also flash rapidly if a processor that does not belong to the patient is detected. (IntelliLink™)*
System Communication Status:	The Auria FireFly lights steadily if the system is successfully transmitting a signal. The Auria FireFly will flicker on/off rhythmically if the system is not transmitting properly. The Auria FireFly will flash rapidly if the processor is on the incorrect patient indicating that stimulation is not being delivered. (see Associating a Patient File With an Implant (IntelliLink™)
PowerCel™/Battery Status	The Auria FireFly will not illuminate if the PowerCel/battery is depleted.

Attaching/Removing an Earhook

Connecting Earhooks

- Align the Earhook flush with the Harmony Processor.
- Hold the Earhook at the base and push to snap in place.
- Gently pull back to confirm that the Earhook is secure.

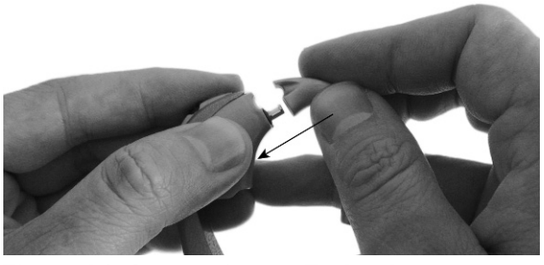

Figure 14: Connecting an Earhook.

Removing Earhooks

- Remove the power source.
- Turn the Earhook slightly more than 1/4 turn in either direction until it comes off.

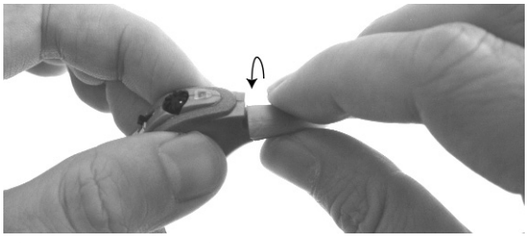

Figure 15: Removing an Earhook.

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Harmony and Auria Accessories

Accent Color Covers and Caps

Accent Color Covers and Caps come in series; Blending, Sophista, Metallic, Techno and Kinder colors. Users can select and easily change the Accent Color Caps and Covers to meet individual preference and lifestyle.

Accent Color Covers are available for both PowerCel configurations and PowerPak configurations (Auria Only). A color cover is held at the base to align on or lift off the processor. Accent Color Caps are placed on the headpiece.

To attach a color cap, align over the headpiece. A piece of metal on the underside of the color cap attracts to the magnet in the headpiece to secure the cap in place.

To change a color cap, gently lift the cap off the headpiece.

Carrying Case

The Carrying Case is a multi-functional case that can carry all the basic Harmony or Auria components. It can hold the processor with any PowerCel configuration, huggie attachment or ear hook. The Carrying Case also contains a removable insert that serves as a Dri-Aid Kit for the convenient removal of any moisture during storage.

Figure 16: Carrying Case

Little Things Wallet

The Little Things Wallet holds either two spare PowerCels and extra ear hooks or a third PowerCel safely and conveniently in a pocket or purse.

Figure 17: Little Things Wallet

PowerCel Charger Car Adapter

The PowerCel Charger Car Adapter charges PowerCels in automobiles by using the accessory power outlet or cigarette lighter.

Figure 18: PowerCel Car Charger Adapter

To use the PowerCel Car Charger Adapter, first insert the adapter into the accessory power outlet or cigarette lighter. Next, connect the plug from the adapter to the PowerCel Charger (where you would typically attach the power supply). Verify that the green light on the charger illuminates, indicating there is power supplied to the charger.

Figure 19: Using the PowerCel Car Charger Adapter

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System Sensor (For use with the PSP, Auria, Platinum and CII BTEs. Not compatible with the Harmony)

The System Sensor is a hand held device that performs a system functionality check. The System Sensor is powered using a lithium battery that will last approximately two years. To use, with the patient (typically a child) wearing the device, place the Sensor over the headpiece at a distance of 1-2 inches. Then gently press the button and the Sensor will display its' status.

- Orange light indicates the System Sensor itself is functioning properly.
- No orange light indicates the battery is depleted in the System Sensor. You will need to obtain a new System Sensor.

Figure 20: System Sensor

Once you have verified the Sensor status (orange light), slowly move the sensor toward the headpiece and observe the system transmitting status as follows:

- Flashing green light indicates the processor battery is charged but the system is not successfully transmitting a signal. Stop and proceed to troubleshooting.
- Solid green light indicates the system is successfully transmitting a signal.
- No green light indicates that the processor battery is depleted and needs to be replaced.

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Behind-the-Ear (BTE) Sound Processors

Prior to the release of the Harmony and Auria, recipients may have received the ear level CII BTE or the Platinum BTE. Both the Platinum and CII BTE can be used for programming in SoundWave for CII and HiRes90K implant users. However, Fidelity 120 is not supported on these processors. The BTE is powered by rechargeable PowerCel. The BTE can store up to three HiResolution programs. A toggle switch serves as a program selector and volume control when programmed in SoundWave. Attaching and removing the PowerCel turns the BTE on and off. The BTE is available in beige or brown with user selectable headpiece color caps available in beige, brown, black, gray, red, or blue.

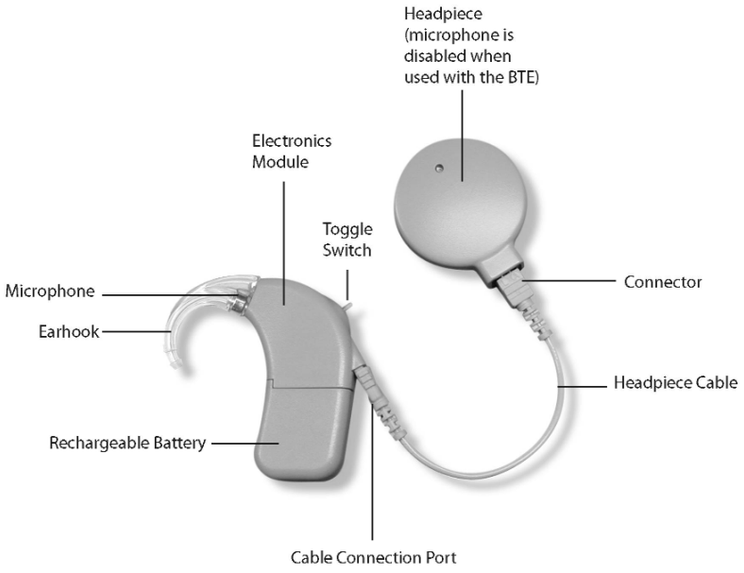

Figure 21: BTE Sound Processor

The following paragraphs in this section refer to both BTEs unless stated otherwise.

Headpiece and Microphone

The BTE features a forward facing omnidirectional microphone housed within the BTE Sound Processor. A headpiece cable connects the BTE to the headpiece. The headpiece microphone is not active when connected to the BTE. One end of the cable is a two pin plug that inserts into the headpiece and the other end is a two-contact plug that connects to the BTE via a connector located immediately below the toggle switch. Cables are available in 3, 4 or 9.5 inch lengths (the longer cable can be used for wearing the processor on the contralateral ear). Headpiece color caps are available in beige, brown, black, gray, red, or blue for user customization. You can adjust magnetic strength by placing additional magnets into the headpiece if needed. The Platinum Headpiece magnet removal tool should be used to change magnets in the headpiece when necessary.

Headpiece (PHP) Color Cap Removal Tool

You can adjust magnetic strength by placing additional magnets into the headpiece if needed. The Platinum Headpiece magnet removal tool should be used to change magnets in the headpiece when necessary.

Figure 22: Headpiece (PHP) Color Cap Removal Tool

Warning: If your patient requires an extra magnet watch for signs of irritation or swelling. After extended use, an extra magnet in the headpiece may no longer be required, and we recommend that you attempt to refit your patient with fewer magnets in the headpiece.

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Earhook

An earhook is used to hold the BTE Sound Processor behind the ear. Three earhooks are available; T-Mic, Auxiliary Audio, and Standard earhooks.

T-Mic® Microphone

The T-Mic is an earhook - microphone combination. The T-Mic is an omni-directional microphone that sits at the opening of the ear. It is preferred by adults for everyday use. The placement of the T-Mic may assist in difficult listening situations, such as in noisy environments or on the phone. The T-Mic works with mobile/cellular phones, even those that cannot be coupled to a telecoil or headsets (simply placed over T-Mic). Remember that in order to use the T-Mic, you must create and download programs with the Audio Mixing ratios set appropriately (100% Aux, that is input from the T-Mic only, is recommended). The T-Mic is available for Platinum or CII BTEs in either a beige or brown color.

Auxiliary Audio Earhook

Auxiliary Audio Earhook has an attached cable used for the purpose of connecting to auxiliary listening devices, such as an FM system or CD player. The auxiliary jack on the Auxiliary Audio Earhook is 3.5mm in size and was designed for stereo plugs. Patients will need to use the auxiliary audio interface cable in conjunction with this connector.

The BTE supports mixing auxiliary audio and microphone signals (Audio Mixing ratios). This allows the patient to listen to an auxiliary sound source, such as a CD player, without losing input from the BTE microphone.

Remember that in order to use an auxiliary device, you must create and download programs with the Audio Mixing ratios set appropriately (typically 50/50 or 30/70 is preferred).

Standard Earhook

The Standard earhook does not include an audio option. It is available in a standard and small size.

Operation

Toggle Switch

The BTE is equipped with a toggle switch that allows the user to change from program to program. In addition to serving as the program switch, the toggle switch also functions as a volume control.

Program Control

The toggle switch changes programs using the following procedures:

- Change from one program to the next by pressing and holding the toggle switch in the upward direction for more than one second. The programs do not round-robin e.g., change to program 1 after program 3.
- Return to previous programs by pressing and holding the toggle switch in the downward direction for more than one second. The programs do not round-robin e.g., change to program 3 after program 1.
- The program changes when you release the switch and it springs back to the mid point.

Volume Control

Patients use the volume control during normal operation to adjust loudness. The default volume is set to a comfortable loudness level for Live Speech during programming in SoundWave. The patient can adjust the loudness level using the toggle. Pressing and then quickly releasing the toggle in the upward direction will increase the volume, while pressing and then quickly releasing the toggle in the downward direction will decrease the volume. There are twenty possible loudness steps, 10 in the upward direction and 10 in the downward direction. The step size and volume range are set during programming. Typically patients require <50% range or a 5% increase per toggle step. Setting the volume range customizes the toggle for each patient and prevents accidental increases in loudness above a patient's comfortable range.

You can also control volume using the volume slider on SoundWave's program window while the patient's hardware is connected to your system.

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BTE Sensitivity

Sensitivity is a program parameter set by the clinician when programming with SoundWave. You can create programs with different levels of sensitivity depending upon individual patient requirements. You will adjust and set sensitivity using the Sensitivity slider on SoundWave's program window. When the sensitivity is set below the defaults setting (decrease dB setting), gain is reduced so that closer, high intensity sounds can be heard such as the patient's own voice or speech from a nearby talker. When the sensitivity is set above the default (increase in dB setting), gain is increased so that softer sounds often at a greater distance from the patient can be heard, but environmental sounds and noise also become more audible. The sensitivity setting is saved with the program.

Program On/Off

The BTE Sound Processor is turned on and off by connecting or removing the PowerCel. When not using the BTE Processor, patients should remove the PowerCel. Otherwise, the BTE remains on and the PowerCel continues to drain. Removing and then replacing the PowerCel will reset the BTE Processor back to the default settings: program 1 and volume settings at default levels.

PowerCel

PowerCels incorporate enhanced capacity to power the CII and Platinum BTEs and permit equivalent processing capabilities of a body-worn processor. PowerCel technology is cost effective. While battery life will vary depending on program settings and patient specific needs, average daily operating times are about 8 hours with the PowerCel Slim and about 16 hours with the PowerCel Plus as well as a greater number of overall recharges for longer PowerCel lifespan. The PowerCel slides onto the BTE to activate the device. The tracks along the PowerCel and BTE direct the PowerCel in place making it easy to use especially for patients with vision or dexterity limitations.

Figure 23: PowerCel Slim and Plus

PowerCel Charger

The PowerCel charger can charge up to four (4) PowerCels, either Slim or Plus, at once. The charger comes with a power supply and international adapters. A green light illuminates on the charger when powered (plugged in).

The charger (shown in Figure 24) contains a light indicating charge status for each PowerCel.

The light is yellow when the PowerCel charging cycle is in progress and turns off when the PowerCel is fully charged. PowerCels slide on to the charger by aligning the pins and tracks and gently sliding in place. To remove a PowerCel from the charger, depress the charger button and gently lift the PowerCel off the charger.

The charge cycle is 3-5 hours. PowerCels do not need to be fully depleted before recharging. Patients should be counseled to rotate their PowerCels to prolong their lifespan The charger is fully compatible with the PowerCels used for the Auria.

Figure 24: PowerCel Charger

Figure 25: Redesigned PowerCel Charger

Figure 25 shows the redesigned charger. There are 2 indicator lights for each PowerCel. When a PowerCel is charging, an amber light located next to the lightening bolt [ ] illuminates. This light will turn off when the PowerCel is fully charged. A red light located next to the exclamation mark [!] illuminates if the charger recognizes any fault with an attached PowerCel, such as when a PowerCel is damaged or the chemistry is depleted (that is, it cannot be recharged anymore). PowerCels are placed on the charger guided by the tracks. To remove, slowly pull the PowerCel off the tracks. The charge cycle is 3-5 hours. PowerCels do not need to be fully depleted before recharging. Patients should be counseled to rotate their PowerCels to prolong their lifespan. The PowerCel charger also comes with a set of power adapters for international use.

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Accessories

System Sensor (For use with the PSP, Auria, Platinum and CII BTEs. Not compatible with the Harmony)

The System Sensor is a hand held device that performs a system functionality check. The System Sensor is powered using a lithium battery that will last approximately two years. To use, with the patient (typically a child) wearing the device, place the Sensor over the headpiece at a distance of 1-2 inches. Then gently press the button and the Sensor will display its status.

- Orange light indicates the System Sensor itself is functioning properly.
- No orange light indicates the battery is depleted in the System Sensor. You will need to obtain a new System Sensor.

Once you have verified the Sensor status (orange light), slowly move the sensor toward the headpiece and observe the system transmitting status as follows:

- Flashing green light indicates the processor battery is charged but the system is not successfully transmitting a signal. Stop and proceed to troubleshooting.
- Solid green light indicates the system is successfully transmitting a signal.
- No green light indicates that the processor battery is depleted and needs to be replaced.

PowerCel Wallet

A PowerCel Wallet is provided for carrying PowerCels in a pocket, purse or keychain. The wallet protects the PowerCel from accidental discharge or damage.

PowerCel Charger Car Adapter

The PowerCel Charger Car Adapter charges PowerCels in automobiles by using the accessory power outlet or cigarette lighter.

Figure 26: PowerCel Car Charger Adapter

To use the PowerCel Car Charger Adapter, first insert the adapter into the accessory power outlet or cigarette lighter.

Next, connect the plug from the adapter to the PowerCel Charger (where you would typically attach the power supply). Verify that the green light on the charger illuminates, indicating there is power supplied to the charger.

Figure 27: Using the PowerCel Car Charger Adapter

Dri-aid Kit

A Dri-aid kit is used to remove moisture from perspiration or humidity from the BTE microphone or electronics.

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Platinum Sound Processor™ (PSP)

The PSP is the body worn processor option for HiResolution® recipients. It is small enough to be worn in a pager-style carrying case at the waist or beltline or in a pouch or harness.

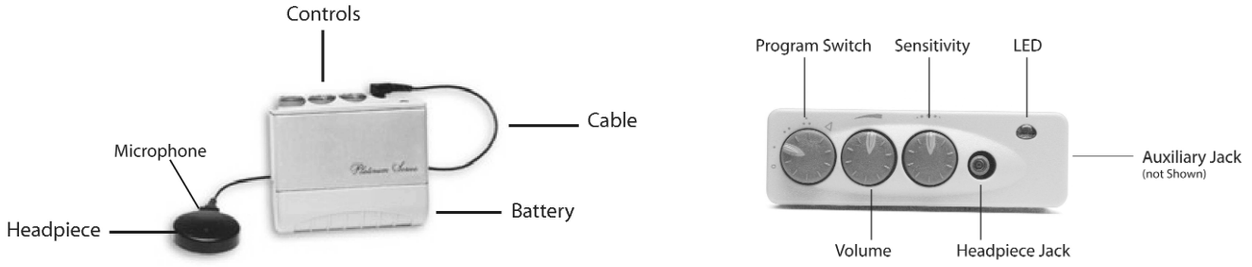

Figure 28: Platinum Sound Processor and Controls

Platinum Headpiece

The Platinum Headpiece integrates the system's microphone and transmitter into a single unit so there is nothing worn on the patient's ear. The headpiece is held in place over the internal receiver by a magnet that aligns itself with the internal magnet in the implant. You can adjust magnetic strength by placing additional magnets into the headpiece if needed. You can use the Platinum headpiece magnet tool to change the magnet when necessary. An omnidirectional microphone is located in the headpiece. The patient can select headpiece color caps in black, grey, beige, brown, red or blue colors. The Platinum Headpiece can be used with the Harmony, Auria, PSP, Platinum BTE and the CII BTE Processors. When used with the other processors, the headpiece microphone is disabled.

Warning: If your patient requires an extra magnet watch for signs of irritation or swelling. After extended use, an extra magnet in the headpiece may no longer be required, and we recommend that you attempt to refit your patient with fewer magnets in the headpiece.

Cables

The cable connects the headpiece to the sound processor and provides the pathway for relaying information. At one end of the cable is a two-pronged plug which is inserted into the headpiece. A small coaxial plug is located at the other end of the cable. This plug is inserted into the headpiece jack in the sound processor.

To remove the cable from the headpiece, always hold the cable's strain relief (the plastic plug) and gently pull it away. The cable should be removed from the headpiece only when it is being replaced. Otherwise, the two-pronged cable plug should remain in the headpiece.

Each cable includes a small clip that can be used to help hold the cable in place. Cables are available in 5 lengths, 18", 24", 32", 42" and 48" and either in a beige or brown color.

Operation

Volume

The patient uses the volume control during normal operation to adjust loudness. The volume control is a rotary dial that adjusts the stimulation level presented to the patient. Typically, Most Comfortable Level (M Level) is set during programming in response to Live Speech with the volume set at 12:00. When rotated clockwise, the volume increases (maximum at 5:00). When rotated counter-clockwise, the volume decreases (minimum at 7:00). The maximum and minimum volume is set by the clinician during programming between -100 to +100% of the dynamic range based on individual user needs. Typically patients require < 50% range. The default setting is -50 to +50%. Setting the volume range customizes the dial for each patient and prevents accidental increases in loudness above a patient's comfortable range.

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Sensitivity

The patient uses the sensitivity control during normal operation to adjust the sensitivity of the microphone.

When the sensitivity control is rotated counterclockwise towards the 7:00 position, gain is reduced so that only high intensity sounds can be heard such as the patient's own voice or speech from a nearby talker. As the sensitivity control is rotated clockwise toward the 5:00 position, gain is increased so that softer sounds often at a greater distance from the patient can be heard, but environmental sounds and noise also become more audible.

Program Switch

The patient uses this control to turn the sound processor on/off (o) and also to select one of three programs (• •• •̣•) that have been created and downloaded to the sound processor during fitting. The Platinum Sound Processor also includes one test position for microphone testing. You can use the test position (Δ) to convert the auxiliary input to an audio output that can be used with earphones to monitor the microphone status.

Auxiliary Audio Input/Output

The patient uses this jack for connecting auxiliary audio equipment such as a portable music player, an FM system, telephone adapter etc. The Platinum Sound Processor supports mixing auxiliary audio and microphone signals. This allows the patient to listen to an auxiliary sound source without losing input from the headpiece microphone. The Audio Mixing ratio is set for each program during device fitting in SoundWave.

You can also use the auxiliary audio input/output jack for testing the headpiece microphone. When the program switch is in the test position, this jack acts as an output to drive the headpiece microphone tester earphones.

System Status Light-Emitting Diode (LED), and Audible Alarms

The Status LED and the Audible Alarm provide you and your patient with information about the status of the sound processor and other hardware components, e.g., microphone, cable.

Audible Alarms

The audible alarm is an optional feature that can be activated at the time of programming. It is designed primarily for children in order to alert parents and teachers when the system is not transmitting sound to the implant or the battery is near depletion. For example, if the child's headpiece falls off the head, the processor will begin to beep and the LED will flash red. When signal is again being transmitted, the LED will stop flashing and the alarm will stop beeping. Additionally, when the battery is near depletion and cannot power the processor, the alarm will emit a periodic beep until the battery dies or is replaced.

Light-Emitting Diode (LED)

The LED (Light-Emitting Diode) indicator is a light located on the control panel adjacent to the headpiece jack. The LED has three primary functions: battery charge status, lock status, and microphone/system status. Depending on the function, the LED will illuminate with either a red or a green light. When the processor is turned on, the LED light will first indicate battery charge status, followed by lock status. The microphone/system status may be checked once lock has been obtained.

Battery Pack Charge Status

To check the battery charge status while the sound processor is in operation, turn the sound processor off and then back on to any program position. The LED light sequence indicates the battery charge status:

- 3 to 4 quick red blinks indicate that the battery is fully charged to power the system
- 2 quick red blinks indicate that the battery is sufficiently charged to power the system
- 1 quick red blink indicates that the battery charge is nearly depleted

Lock Status

Once the battery charge sequence is complete, the LED indicator begins to flash red approximately once per second. Flashing will continue until the headpiece is properly positioned on the head. Once the ICS receives the signal transmitted by the headpiece, the flashing will stop. (The LED indicator may only flash once.) You can program the audible alarm to sound along with the red LED to indicate lock status.

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Microphone/System Status

The LED flashes green when the signal is in compression. This occurs when a loud acoustic signal (e.g. snapping fingers) is presented close to the headpiece with the sensitivity at the default setting. Note that the illumination of the LED indicates that the sound processor is starting to compress the audio signal, so as the sensitivity control setting is increased, the LED illuminates with lower levels of sound. The LED flashing green in this condition indicates the following:

- the program's AGC is enabled
- the microphone is receiving sound
- the sound processor is sending data to the ICS
- the ICS is correctly receiving the data
- the ICS is sending data back to the sound processor
- the sound processor is correctly receiving this information

Battery

A lithium ion rechargeable battery pack or a pack containing three standard AA batteries powers the PSP. The rechargeable battery pack will need to be changed approximately once per day for most patients, depending on the program and individual power requirements. The battery pack slides in place guided by tracks along the battery and the processor. A latch on the side of the processor secures the battery in place. The battery can only be properly inserted one way. When the sound processor is not in use, it should be turned off; otherwise, the battery will continue to drain. A battery pack option that utilizes 3AA alkaline or rechargeable batteries is also available.

Figure 29: Platinum Sound Processor with Battery Detached

Figure 30: PSP Battery Charger

Battery Charger

The battery charger will recharge two battery packs simultaneously and has a charging cycle of approximately 2.5 hours. Along the side of the charger are four LED indicators, two for each battery, which indicate charge status. A yellow light displays while the battery is charging. This light changes to green when the battery charging cycle is complete. Batteries do not need to be fully depleted before recharging. Patients should rotate batteries to promote battery life.

Accessories

Headpiece Microphone Tester Earphones

The headpiece microphone tester earphones allow a subjective listening assessment by the clinician or caregiver of the quality of sound as it is received by the headpiece microphone. Intermittences in the headpiece cable can also be detected.

Telephone Adapter

The telephone adapter is provided as an alternative to placing the telephone receiver next to the microphone of the headpiece or auxiliary microphone. There are two styles available depending on patient need. The Platinum Series phone Adapter designed for the PSP system comes with the kit. Other options for coupling the phone to the PSP are available from Advanced Bionics or other sources.

Auxiliary Microphone

Some patients find that using the Auxiliary Microphone is preferable in some, or all listening environments. The Auxiliary Microphone can be hand-held or worn on a lapel or collar.

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Carrying Case

The adult patient kit comes equipped with a quality leather carrying case that snaps securely over the SP. A clip on the back of the case secures it to the patient's waistband or belt.

Harness

The pediatric patient kits come equipped with a harness that contains a pocket for securing the processor. Harnesses are left or right specific and should be worn on the same side as the implant.

Care and Maintenance of the Harmony, Auria, BTE or PSP

The processor should be wiped off with a dry, lint free cloth. The contacts on the battery module or PowerCel and processor should be kept clear of dirt and debris. The processors should not get wet or submerged in water or other fluid. The processors should be stored in the provided case and not exposed to extreme temperatures, either hot or cold. The normal operating range is 32° F (0° C) to 115° F (45° C).

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Patient Equipment Model Numbers

The following tables detail patient equipment with the corresponding Advanced Bionics model number.

Table 3: Internal Device

Description	Model No.
CII Bionic Ear/HiFocus	AB5100H-11A, AB-5100H-12A
HiRes 90K	CI-1400-01; CI-1400-02H

Table 4: Harmony and Auria External Equipment and Accessories

Description	Model No.
Harmony	CI-5235-xxx
Auria	CI-5230-xxx
HiRes 90K Auria Headpiece	CI-5304-xx3
Auria Headpiece for CII Implant Patients	CI-5304-xx4
HiRes90K Platinum Headpiece	AB-7300-001
Platinum Headpiece for CII Implant Patients	AB-7300
Auria Accent Color Covers, Slim Auria Accent Color Covers, Plus	CI-7120-xxx CI-7121-xxx
Standard Earhook	CI-5730-xxx
T-Mic Earhook	CI-5830-xxx
System Sensor (not compatible with Harmony)	CI-5820
FireFly Earhook (Auria only)	CI-5720-xxx
Direct Connect Earhook	CI-5840-xxx
iConnect Adapter	CI-5751-xxx
Direct Connect Cables	CI-5841-xxx
T-Coil (external)	CI-5750
PowerCel Slim PowerCel Plus	CI-5520-xxx CI-5540-xxx
PowerCel Accent Color Covers, PowerPak	CI-7122-xxx
PowerPak (Auria only)	CI-7400-xxx
Accent Color Cover Headpiece Caps	CI-7123-xxx
PowerCel Charger	CI-5600-xxx
PowerCel Charger Power Supply	CI-5610-xxx
PowerCel Charger Adapters (3)	CI-5630
PowerCel Charger Car Adapter	AB-5620-xxx
Auria Carrying Case	CI-7420
Travel Case	CI-7420-xxx
Little Things Wallet	CI-7115-xxx
PowerCel Wallet	CI-7115-xxx

Note: The Harmony Processor (CI-5235) is incompatible with the Auria FireFly (CI-5720), Auria AA PowerPak (CI-7400), and System Sensor (CI-5820). The FireFly and System Sensor, if used with the Harmony Processor, may result in false diagnostics. If the AA PowerPak is used to power the Harmony Processor, the processor's LED Status Indicator may falsely indicate low battery. In rare instances, using the AA PowerPak with the Harmony may cause the PowerPak's fuse to trip thereby rendering the PowerPak useless. All other Auria accessories are for use with both the Auria and Harmony Processors.

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Table 5: PSP External Equipment and Accessories

Description	Model No.
Platinum Sound Processor	AB-7250
Platinum Headpiece for CII Implant Patients	AB-7300-xxx
HR90K Platinum Headpiece	AB-7300-001
Rechargeable Battery Packs with Covers	AB-7500
AA Battery Compartment for PSP	AB-7510
Battery Charger	AB-7600
Battery Charger Power Supply	AB-7610
Battery Charger Power Cord	AB-7620, 7630, or 7640
Battery Charger Car Adapter	AB-5620
Headpiece Cables	MMT-5401R, MMT-5401RB, MMT-5402R, MMT-5402RB, MMT-5403R, MMT-5403RB, MMT-5404R, MMT-5404RB, MMT-5405R, MMT-5405RB
Auxilliary Microphone (Lapel Mic)	AB-7700
Leather Carrying Case (Adult)	AB-7420-xx
Harness and Case (Child)	AB-7440-xxx
Sport Case	AB-7430-xx
Hip Patch Case	AB-7450-36
Child's Multi-colored Belt	AB-5660
Telecoil Pickup	AB-7750
Telephone Adapter	AB-8750
Headpiece Microphone Tester Earphones	AB-7760

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Table 6: BTE External Equipment and Accessories

Description	Model No.
CII BTE Sound Processor	CI-5220-xxx
Platinum BTE Sound Processor	CI-5210-xxx
Platinum Headpiece	CI-7300-xxx
PowerCel Slim PowerCel Plus	CI-5522-xxx CI-5541-xxx
PowerCel Charger (Auria and BTEs)	CI-5600-xxx
PowerCel Charger Power Supply	CI-5610-xxx
PowerCel Charger Power Supply Adapters (Set of 3)	CI-5630
User Reference Binder	7095339-xxx
3 inch Cable	CI-5403-xxx
4 inch Cable	CI-5404-xxx
9.5 inch Cable	CI-5409-xxx
BTE Earhook	Standard: CI-5700-010 Small: CI-5700-020
Carrying Case	CI-7410-01, -02
Dri-Aid Kit	CI-7301
Charger Travel Case	CI-7250
Little Things Wallet	Black Leather: CI-7115-401
Instructional Video	CI-8230
Audio Interface Cable	CI-5815
Auxiliary Microphone	CI-5810
Auxiliary Audio Earhook	CI-5705 -010 (large), -020 (small)

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Clinician Equipment

Cochlear implants are highly specialized devices that must be adjusted to suit each individual patient. You will use a computer running SoundWave Professional Suite software, the Clinical Programming Interface (CPI), and the patient's own sound processor to create individualized programs for each patient. The CPI and the programming cable link your PC and the patient's sound processor. An RS-232 computer cable connects the CPI to a 9-pin male RS-232 or USB port on your computer. If a USB port is being used a USB to Serial Adapter is required.

The fitting system is shown in the picture below.

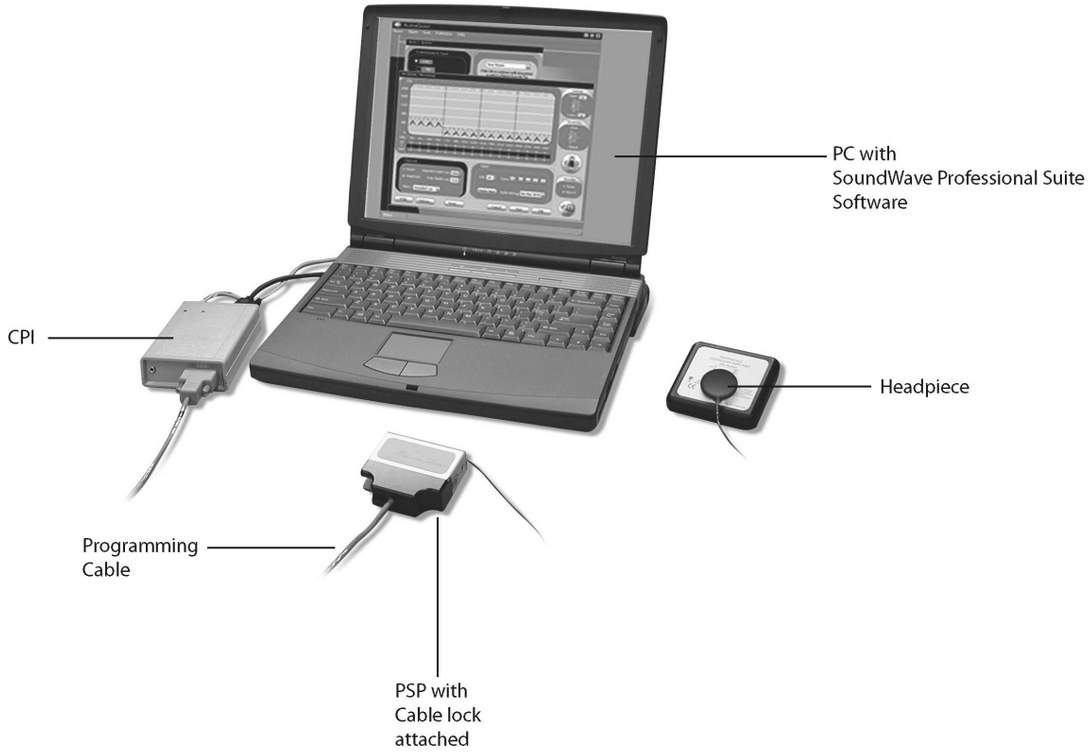

Figure 31: Clinical Programming System

You will use the following tools when fitting a patient:

- SoundWave installed and running on a PC. You will use SoundWave to create, customize, and download programs to your patient's sound processor.
- Clinical Programming Interface (CPI) — Provides a bridge between the computer's serial or USB port and the sound processor. Additionally, the CPI provides power to the connected sound processor during the fitting procedure.
- Clinical Programming Interface Power Supply and Cord — The CPI power supply is connected to a standard wall outlet, and to the back of the CPI. NEVER USE ANOTHER POWER SUPPLY WITH THE CPI. Always use the one provided for the CPI by Advanced Bionics.
- Sound processor — The patient's own sound processor is used during device fitting. Remove the battery to access the connector that attaches the appropriate programming cable from the sound processor to the CPI.
- Programming Cable — Separate programming cables are required for the body-worn and the ear level processors. All BTEs use the same programming cable. A switch box may be utilized to switch between ear level and body-worn programming cables. A lock is available to help secure the programming cable to the PSP. It slides onto the sound processor like the battery. The BTE cable lock is built in to the BTE programming cable.

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Minimum Hardware and Software Requirements

SoundWave will run on the Windows 98 Second Edition (SE), Windows 2000 Pro, and Windows XP Home and Professional operating systems. The following table lists the recommended requirements for each of the supported operating systems.

Table 7: Hardware and Software Minimum Requirements

Component	Windows 98SE	Windows 2000 Pro	Windows XP Home and Professional
Memory	32 MB RAM	64 MB RAM	128 MB RAM
Processor	P2/300 MHz	P3/500 MHz	P3/600MHz
Hard Drive	100 MB	100 MB	100 MB
Video Resolution and Color Setting	800 x 600 256 Colors	800 x 600 256 Colors	800 x 600 256 Colors

Clinician Equipment Model Numbers

The following table details the model numbers for all clinician programming equipment.

Table 8: Clinician Equipment Model Number

Description	Model No.
Clinical Programming Interface (CPI) inludes RS-232 serial cable	AB-6500
PSP Programming Cable	AB-6510
Cable Lock (PSP)	AB-6535
CPI Power Supply	AB-6521
CPI Power Cord (US) * also requires AB 6521	AB-7620
CPI Power Cord (UK) * also requires AB 6521	AB-7640
CPI Power Cord (EU) * also requires AB 6521	AB-7630
SoundWave Fitting Software	CI-6055
BTE Programming Cable	CI-6401

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Connecting Clinician Equipment

The sound processor is connected to the system via the programming cable. The programming cable is installed by first connecting one end to the 15-pin connector on the front panel of the CPI. The other end is connected to a connector in the sound processor in place of the battery or PowerCel.

The patient is connected to the system when his/her headpiece cable is plugged into the sound processor and the headpiece is locked with the implant.

Caution: The CPI powers the sound processor during fitting. If you connect your patient prior to opening SoundWave, your patient's processor will function as though it had a battery, e.g., the patient's processor is active and the patient hears as usual. When using a loaner sound processor with a patient, make sure that you start SoundWave before you connect the processor. If you do NOT, and the programs on the processor were not created for that patient, unwanted stimulation will occur.

What You Will Need

- PC with Windows XP operating system (Windows 2000 and Win 98 SE also compatible)
- CPI Power Supply and power cord
- CPI and RS-232 cable
- USB adapter cable (if using USB port to connect CPI)

Connecting the CPI to the Computer

You will use the Serial port or the USB port to connect the CPI and your computer.

Serial Port Connection

1. Connect the RS-232 cable on the Clinical Programming Interface (CPI) to the serial port on the back of your computer.

2. Connect the CPI power supply cord to the CPI and the external power source.
   A green light illuminates on the CPI indicating power is flowing to the unit.
3. Connect the programming cable to the front of the CPI and then to the sound processor.

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USB Connection

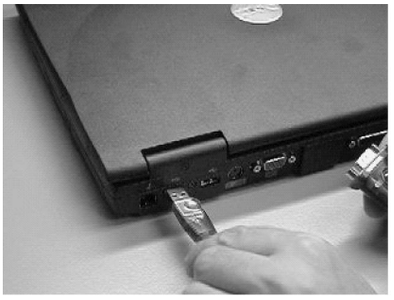
This diagram details the USB connection.

CPI ⟶ RS-232 ⟶ USB ⟶ USB Port
CPI Adapter Cable

First, install the USB to Serial Adapter Cable Software driver program following the instructions provided with the adapter cable. This is only necessary the 1st time you install SoundWave and connect the fitting system hardware.

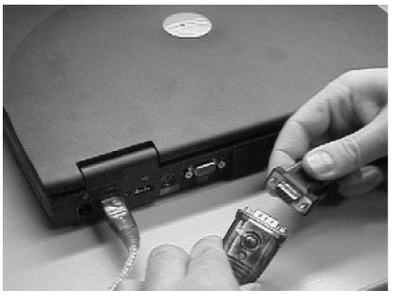
Note: Please contact Advanced Bionics for support prior to installing USB adapters for use with SoundWave.

1. Plug the USB connector into the USB port on the back of your computer.



2. Connect the RS-232 cable to the USB Adapter cable.

Note: If needed, a compatible USB to Serial Connector can be purchased through Advanced Bionics (Part # 5093159-001)



3. Connect the other end of the RS-232 cable to the CPI as usual.
4. Connect the CPI power supply and cable as usual.

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System Safety

Equipment Safety

Caution: The CPI Power Supply is a high voltage device and should be used with caution. ALWAYS USE THE POWER SUPPLY THAT IS PROVIDED WITH THE CPI. FAILURE TO DO SO MAY CAUSE DAMAGE TO THE CPI.

Please observe the following precautions:

- The CPI and the sound processor are both low voltage (5 volt) devices posing no threat of electrical shock.
- The international version can be used world-wide in the range between 100 VAC/60Hz and 240 VAC/50Hz.
- Check the power cords with each use for frayed or exposed wires. Also inspect the power plug prongs to assure that they are in good condition. Immediately replace the equipment if problems are noted.

Software Safety

SoundWave is compatible with SCLIN2000 and therefore may be installed on the same computer. It is recommended that other software packages (hearing aid manufacturers, other CI manufacturers, appointment scheduling software) not be resident on the same computer used to program Advanced Bionics devices. Other software packages may compromise the software speed and stability. Should you have any questions about the software, please contact Advanced Bionics.

All patient data are stored in a database on the hard disk of the computer. Although the database is protected, it can still be destroyed or lost. We recommend that all patient data be backed up on a regular basis, either daily, weekly or after each fitting, whichever is less frequent. If these precautions are taken, the entire database can be restored. If the database is lost and not recoverable for some reason, programs that were sent home with patients can be uploaded from their SPs. However anything else associated with patient files will be lost.

Note: The use of shareware programs uploaded from bulletin boards greatly increases the probability of a virus infection.

Patient Safety

Caution: It is possible to present loud unexpected stimulation to the patient if proper procedures are not followed. Use the following checklist to avoid such an incident:

The HiResolution Bionic Ear System is designed to protect your patient from unintended stimulation utilizing several safety measures for both the software and hardware. These safety measures include: blocking capacitors, clipping values, and two levels of software checks. In addition, an Implant association feature called IntelliLink™ has been implemented in the SoundWave software. This feature associates a patient's implant with the patient file. As such, programs created in the file with this association feature implemented will not stimulate another patient. This applies to programs from the patient file downloaded to any processor.

- Start SoundWave before connecting a processor
- Before turning on stimulation, be sure that the stimulation level is not above previously measured levels for your patient
- Always check the sound processor to assure that the volume control is at the minimum setting, and the sensitivity control is at the mid point or below before using live-voice stimulation.
- Turn on stimulation before increasing the levels.

Although precautionary measures have been implemented in the software to prevent unwanted stimulation, it is the clinician's responsibility to ensure that such occurrence is prevented. The software provides the following features to prevent unwanted stimulation.

- The clinician is always notified when stimulation is taking place by a visual and/or auditory indicator.
- Stimulation is immediately terminated when a loss of lock (i.e., loss of power to the ICS) is first detected.
- Stimulation is immediately terminated when the clinician hits the space bar on the keyboard.
- Hardware clipping registers are set by the software to limit the upper level of stimulation.

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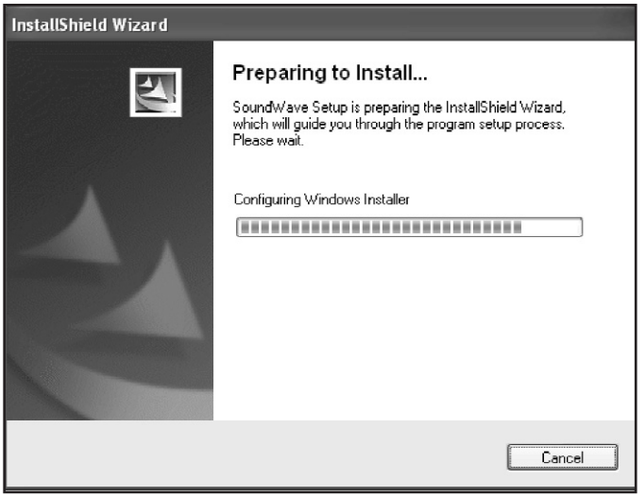
Installing SoundWave Professional Suite

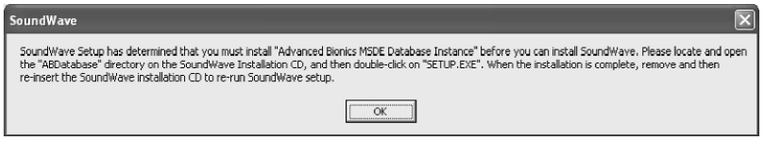
You will install SoundWave Professional Suite using the installation CD that is provided with this manual. SoundWave uses a database program called ***Advanced Bionics MSDE Database Instance*** which must be installed prior to and only on the first SoundWave installation. This program is also found on the SoundWave installation CD.

Installing Advanced Bionics MSDE Database Instance

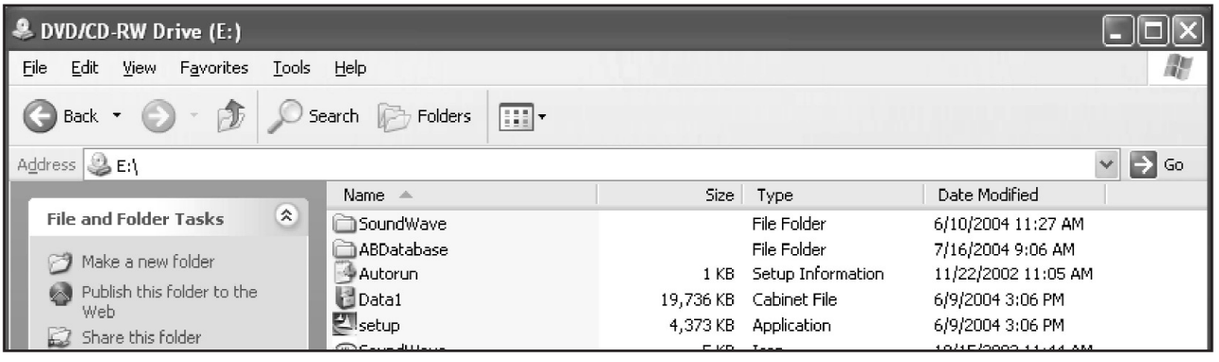
1. Insert the CD in your CD drive.
   The system automatically begins to prepare for installation and displays the following page.


InstallShield Wizard
Preparing to Install...
SoundWave Setup is preparing the InstallShield Wizard, which will guide you through the program setup process. Please wait.
Configuring Windows Installer
Cancel

SoundWave setup looks to see if the Advanced Bionics MSDE Database Instance has already been installed on your PC. If it has not, SoundWave displays the following message.


SoundWave
SoundWave Setup has determined that you must install "Advanced Bionics MSDE Database Instance" before you can install SoundWave. Please locate and open the "ABDatabase" directory on the SoundWave Installation CD, and then double-click on "SETUP.EXE". When the installation is complete, remove and then re-insert the SoundWave installation CD to re-run SoundWave setup.
OK

2. Click on the ***OK*** button.
3. Navigate to your CD drive,


DVD/CD-RW Drive (E:)
File Edit View Favorites Tools Help
Back Search Folders
Address E:\
Go
File and Folder Tasks
Make a new folder
Publish this folder to the Web
Share this folder
Name Size Type Date Modified
SoundWave File Folder 6/10/2004 11:27 AM
ABDatabase File Folder 7/16/2004 9:06 AM
Autorun 1 KB Setup Information 11/22/2002 11:05 AM
Data1 19,736 KB Cabinet File 6/9/2004 3:06 PM
setup 4,373 KB Application 6/9/2004 3:06 PM

4. Locate the directory called ***ABDatabase***, and then double-click on it to open it.

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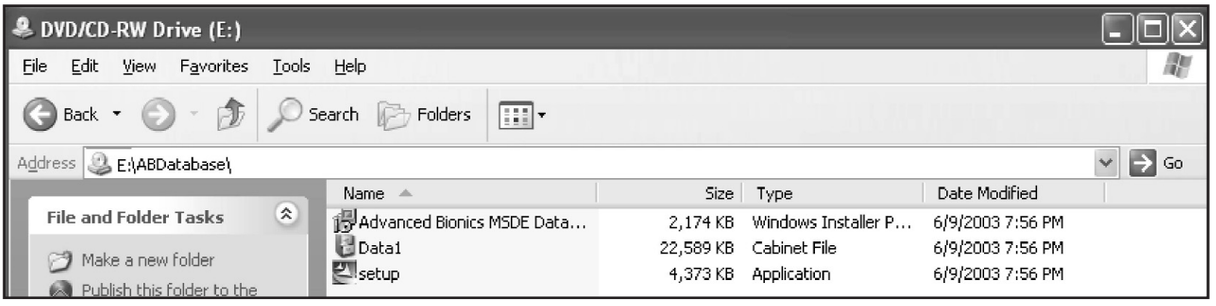
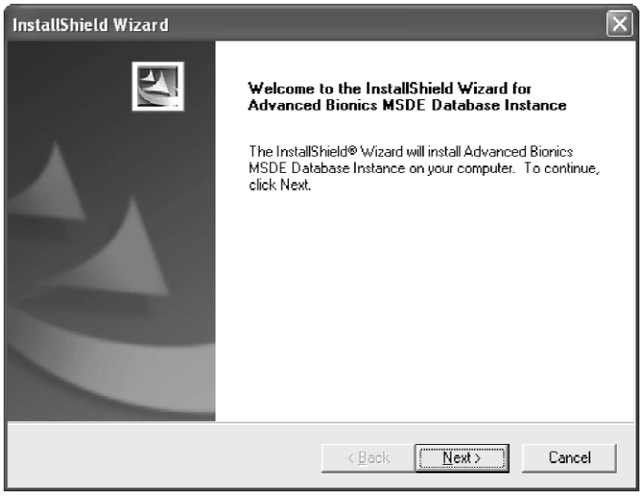
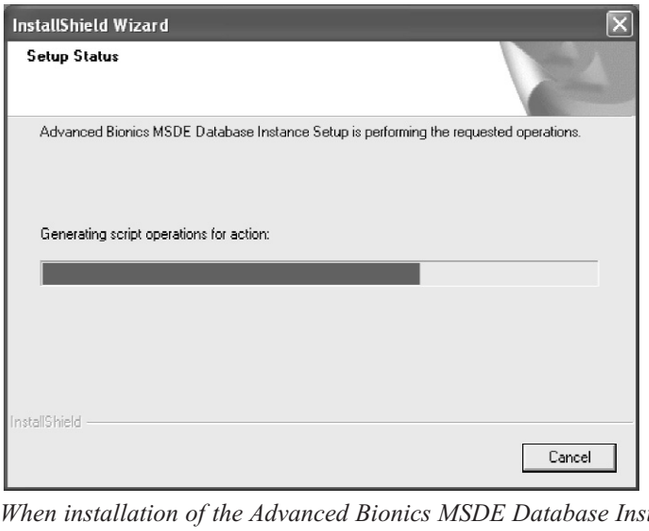

DVD/CD-RW Drive (E:)
File Edit View Favorites Tools Help
Back Search Folders
Address E:\ABDatabase\
Go
File and Folder Tasks
Make a new folder
Publish this folder to the
Name Size Type Date Modified
Advanced Bionics MSDE Data... 2,174 KB Windows Installer P... 6/9/2003 7:56 PM
Data1 22,589 KB Cabinet File 6/9/2003 7:56 PM
setup 4,373 KB Application 6/9/2003 7:56 PM

5. Double-click on ***setup.exe***.
The system prepares to install the Advanced Bionics MSDE Database Instance.


InstallShield Wizard
Welcome to the InstallShield Wizard for Advanced Bionics MSDE Database Instance
The InstallShield® Wizard will install Advanced Bionics MSDE Database Instance on your computer. To continue, click Next.
< Back
Next >
Cancel

6. Click on ***Next***.
The system begins installation of the Advanced Bionics MSDE Database Instance and displays the progress of the installation.



When installation of the Advanced Bionics MSDE Database Instance completes, the system displays the following page.

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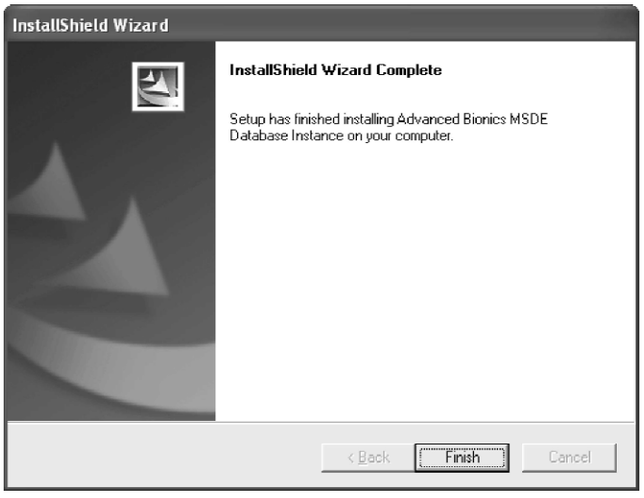

7. Click on ***Finish***.
8. Remove and re-insert the SoundWave installation CD. SoundWave Setup will automatically start.

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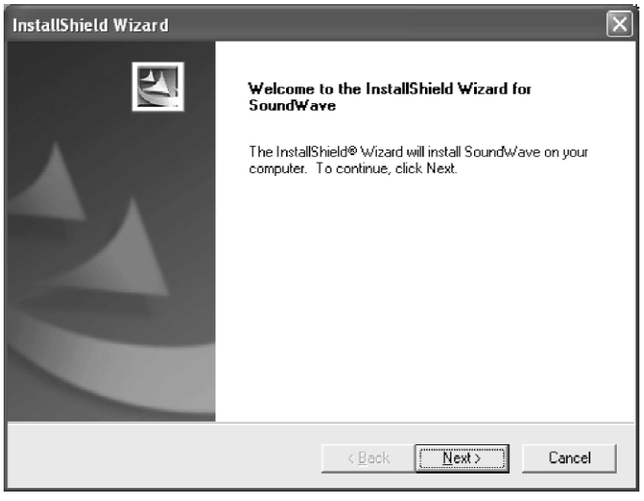
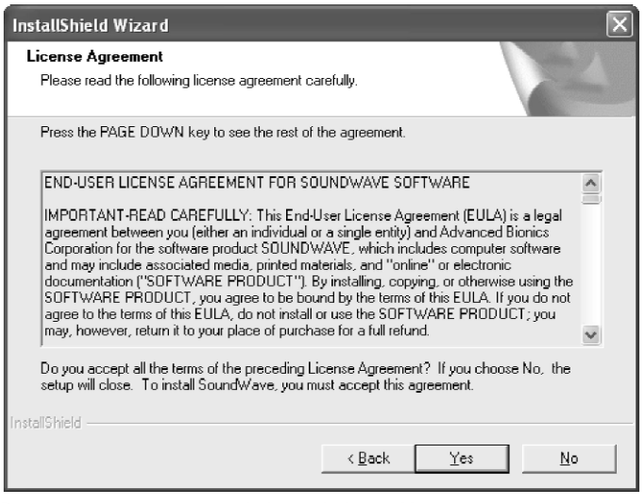
Installing SoundWave

1. Insert the CD in your CD drive.
   The system automatically begins to prepare for installation and then displays the following page.


InstallShield Wizard
Welcome to the InstallShield Wizard for SoundWave
The InstallShield® Wizard will install SoundWave on your computer. To continue, click Next.
< Back
Next >
Cancel

2. Click on ***Next***.
   SoundWave setup displays the License Agreement.


InstallShield Wizard
License Agreement
Please read the following license agreement carefully.
Press the PAGE DOWN key to see the rest of the agreement.
END-USER LICENSE AGREEMENT FOR SOUNDWAVE SOFTWARE
IMPORTANT-READ CAREFULLY: This End-User License Agreement (EULA) is a legal agreement between you (either an individual or a single entity) and Advanced Bionics Corporation for the software product SOUNDWAVE, which includes computer software and may include associated media, printed materials, and "online" or electronic documentation ("SOFTWARE PRODUCT"). By installing, copying, or otherwise using the SOFTWARE PRODUCT, you agree to be bound by the terms of this EULA. If you do not agree to the terms of this EULA, do not install or use the SOFTWARE PRODUCT; you may, however, return it to your place of purchase for a full refund.
Do you accept all the terms of the preceding License Agreement? If you choose No, the setup will close. To install SoundWave, you must accept this agreement.
InstallShield
< Back
Yes
No

3. Read the agreement and then click on ***Yes***.
   The system displays the Customer Information page.

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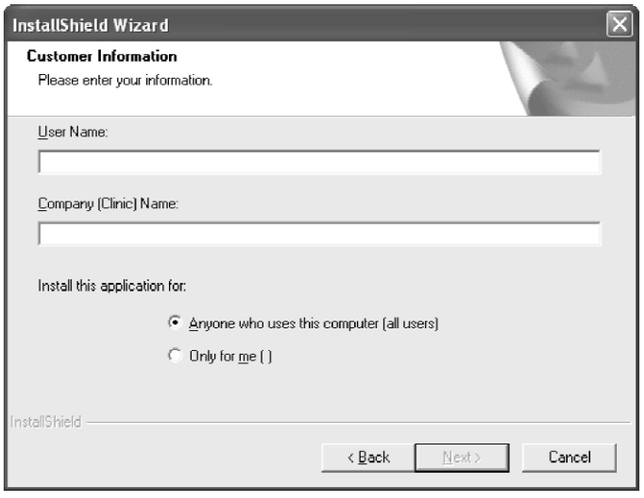
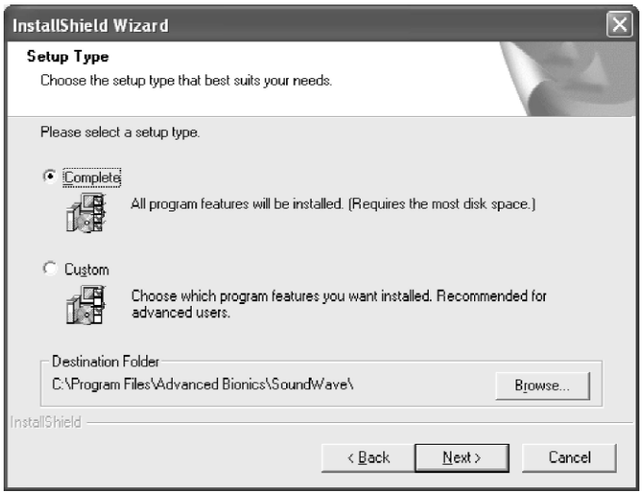


4. Enter your User Name and the name of your Clinic or Company and then click on ***Next***.
The system displays the Setup Type page. The default is Complete.



5. Click on ***Next***
SoundWave setup begins installation and indicates progress in the Setup Status page.

When installation is complete…

6. Click on ***Finish***.
SoundWave setup is complete.

During installation the SoundWave application and Help icons are placed on your desktop.

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Upgrading SoundWave

If you have already been using SoundWave, you will need to update to the new version now being released. The process is automatic and will not harm your patient database. However, as a precaution, we recommend that you backup your database prior to installing a new version of SoundWave. Instructions for backing up your database can be found in Chapter 2 of this manual.

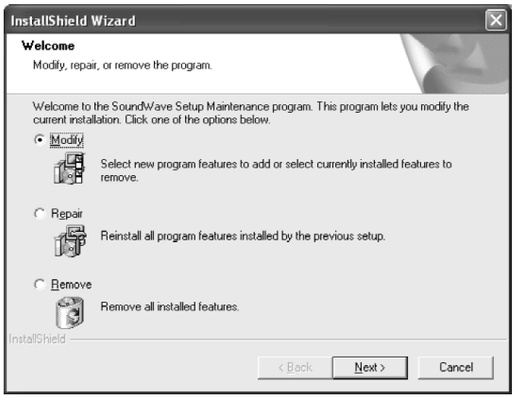
1. Insert the CD in your CD drive.
   The system automatically begins to prepare for installation and then displays the following message.

2. Click on ***Yes*** and then follow the on-screen instructions.
   The installer updates SoundWave.

Reinstalling or Uninstalling SoundWave

If you need to reinstall the current version of SoundWave, the process is much the same as first time installation. The installer will detect that a current version of SoundWave resides on your computer. The process is automatic and will not harm your patient database.

1. Insert the CD in your CD drive.
   The system automatically begins to prepare for installation and then displays the following message.


InstallShield Wizard
Welcome
Modify, repair, or remove the program.
Welcome to the SoundWave Setup Maintenance program. This program lets you modify the current installation. Click one of the options below.
Modify
Select new program features to add or select currently installed features to remove.
Repair
Reinstall all program features installed by the previous setup.
Remove
Remove all installed features.
InstallShield
< Back
Next >
Cancel

Modify - Allows you to choose to make modifications to a previous installation. You will unlikely ever use this option.
Repair - Choose this option if your installation has become corrupted.
Remove - Choose this option to uninstall SoundWave.

2. Make your selection and then click on ***Next***.
   The system performs the selected operation.
3. When installation is complete, click on ***Finish***.

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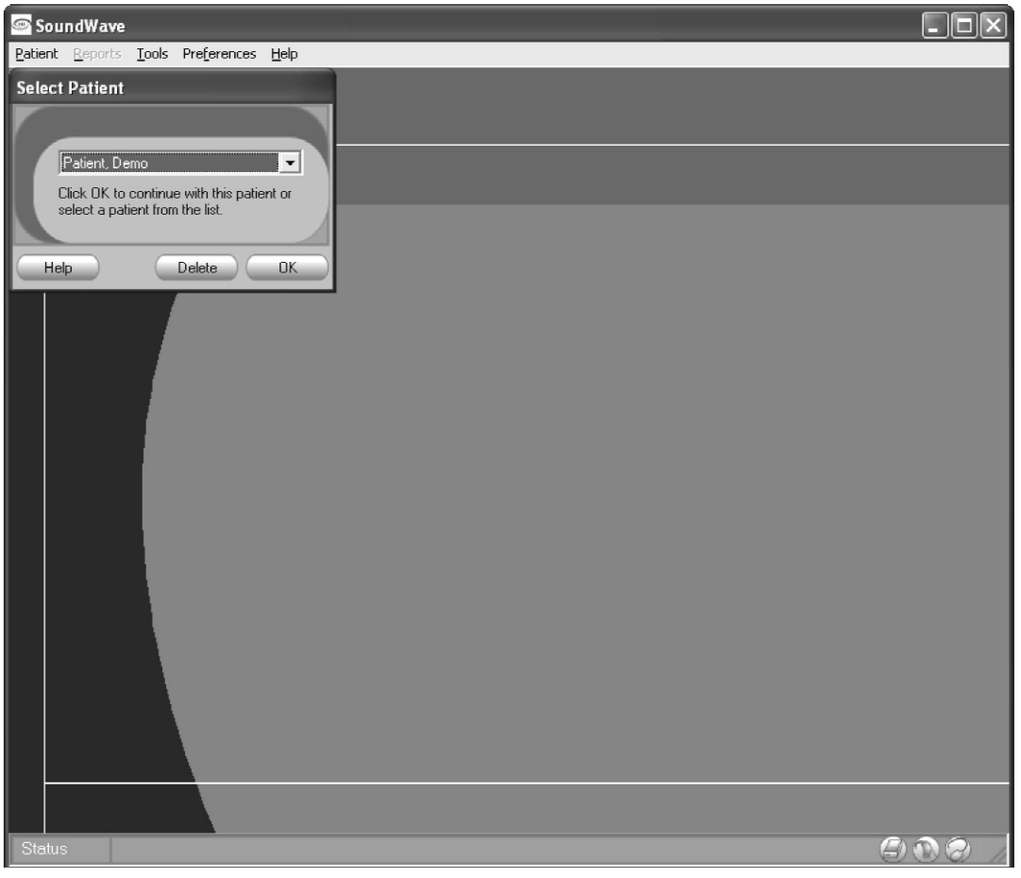
Starting SoundWave

Caution: The CPI powers the sound processor during fitting. If you connect your patient prior to opening SoundWave, your patient's processor will function as though it had a battery, e.g., the patient's processor is active and the patient hears as usual. When using a loaner sound processor with a patient, make sure that you start SoundWave before you connect the processor. If you do NOT, and the programs on the processor were not created for that patient, unwanted stimulation may occur. Use the IntelliLink™ feature as a safeguard!

1. To start SoundWave, double-click on the SoundWave desktop icon.

SoundWave starts and displays the Main and Select Patient windows.



2. Connect the patient's sound processor to the CPI.

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When You Need Help

Help is available from most of the SoundWave windows. It was designed as an aid to familiarize you with SoundWave and to answer questions about the software.

To Access Help:

Click on the Help option on SoundWave's main menu.
OR
Click on the Help button on any of SoundWave's windows.

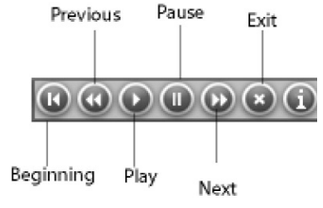
The Help is organized into logical topics with step-by-step instructions on how to complete the things you will need to do using this software. In addition, from time to time you will see the following graphic within the help system.

Show Me

The camera indicates that a short movie clip is available to show you exactly how to perform the operation that is being described. Just click on the camera and watch the movie.

Note: ***You may not be able to see the entire screen of some of the movies if your screen resolution is at 800 x 600. You can remedy this by changing your screen resolution to 1024 x 768. Right click anywhere on your desktop, and then click on Properties. Click on the Settings tab and then move the Screen Resolution slider to 1024 x 768.***

There are controls at the bottom of the movie screen that you can use to slow down, speed up, repeat or end the movie.



Beginning	Rewinds the movie to the beginning
Previous	Goes back one frame of the movie
Play	Plays the movie, or re-starts the movie if pause has been pressed.
Pause	Pauses the movie until play is clicked.
Next	Moves the movie forward one frame
End	Ends the movie and closes the web browser

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SOUNDWAVE™

PROFESSIONAL SUITE

Using SoundWave

HARMONY™

HiResolution Bionic Ear System

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SoundWave™ Professional Suite

You will use SoundWave to fit the HiResolution® Bionic Ear System. All patients with CII and HiRes90K implants can be programmed in SoundWave with HiResolution sound processing. In this chapter, we will describe SoundWave's three (3) principal windows and take you through an initial fitting from creating a new patient file to downloading created programs to your patient's processor. You can find a definition of terms following the Table of Contents.

SoundWave Features

Electrode Conditioning

Electrode conditioning prepares the electrodes for stimulation prior to programming. The introduction of low level current removes any protein build up or air bubbles from any electrodes. Impedances will then be measured in conjunction with electrode conditioning. Electrode conditioning is only necessary for a patient's first fitting in SoundWave, or when enabling electrodes that have not been used for some time. Impedances are also measured when:

- A patient file is initially opened providing that the processor is connected.
- A processor is connected and the patient file is already open.

Clinical Units (CU)

Loudness growth is controlled by pulse amplitude and pulse duration. This relationship may be expressed as pulse amplitude x pulse width. The product is referred to as charge. In SoundWave, Clinical Units represent constant charge (amplitude x pulse width x k, where k = an arbitrary scaling constant) on a scale of 0-6000 CU. Clinical Units are also referred to as "Charge Units" in SoundWave.

Automatic Pulse Width

SoundWave automatically adjusts pulse width during programming to maintain fast rates at the narrowest pulse width within system compliance. The algorithm takes into account each patient's unique physiology and M levels and performs all the necessary computations each time M levels are changed. The CU represents constant charge. Therefore, as adjustments in pulse width are made, charge is kept constant (CU remains the same) eliminating the need to re-measure levels when pulse width is changed.

Auto-T

Auto-T refers to the automatic setting of threshold levels during programming. T levels are set at 1/10th of M across each electrode. You are not required to set T levels on an electrode-by-electrode basis, saving time and preventing patient fatigue.

Speech Bursts

Speech Burst is the default stimulation used for the setting of M levels. Speech Bursts are band-pass filtered white noise delivered at rates equivalent to Live Speech stimulation. Speech bursts are delivered to 3 to 4 electrodes simultaneously, depending on the number of active electrodes. Using Speech Bursts reduces the number of active loudness judgments required by the patient, and is more representative of dynamic Live Speech stimulation delivered during daily device operation.

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Power Estimator (PoEM)

PoEM represents an advanced approach for transparent management of RF. PoEM generates a table (taking less than 1 second) each time a patient is locked to the system that specifies the needed RF for a given stimulation level. The table is referred to during device operation before a stimulus is sent to the implant to adjust RF based on the dynamic input of various listening environments. PoEM improves lock stability across listening environments, for changes in patient skin flap thickness that naturally occur over time, and between various hardware configurations (that is when you change cables, headpieces or processors). Therefore, with PoEM, a program created on a PSP could be downloaded directly to a BTE, Auria, or Harmony and the RF would automatically adjust to the change in hardware. In addition, PoEM often improves battery life.

Power Economy Mode (Harmony only)

Power Economy Mode provides a significant increase in battery life. This option is enabled by default. Only disable if you have difficulty maintaining lock during programming. You can enable or disable this option during processor initialization. This is a processor specific parameter and therefore applied to all programs. If you must disable this option, be sure to verify the need to continue to keep it disabled during follow-up visits.

HiRes®

Advanced sound processing strategies that are designed to more accurately represent sound. The following HiRes options are available: HiRes-P, HiRes-S HiRes-P with Fidelity 120 and, HiRes-S with Fidelity 120.

Programming HiRes with HiRes Fidelity 120: Within the United States of America (USA), only adults (with postlingual onset of severe or profound hearing loss) with at least 3 months experience with HiRes and who have the cognitive ability to choose the sound processing options can be provided with the HiRes Fidelity 120. All the other patients are to be fit with HiRes (HiRes-S or HiRes-P) programs only.

Neural Response Imaging (NRI)

Neural Response Imaging (NRI) is the method by which we can measure responses from the auditory nerve using the HiResolution® Bionic Ear System. Using the system's telemetry, one electrode is used to stimulate nerve fibers, while another electrode is used to measure the resulting electrical activity. The ability to measure neural responses is highly dependent on neural survival, the stimulus used, and the recording technique. A neural response is a small change in voltage that occurs when neurons fire in synchrony. NRI is a tool used either intra-operatively or postoperatively. NRI can assist the clinician by providing a general indication of program levels, confirmation of neural function, and an assessment of device functionality.

NRI is discussed in detail in Chapter 3 of this manual.

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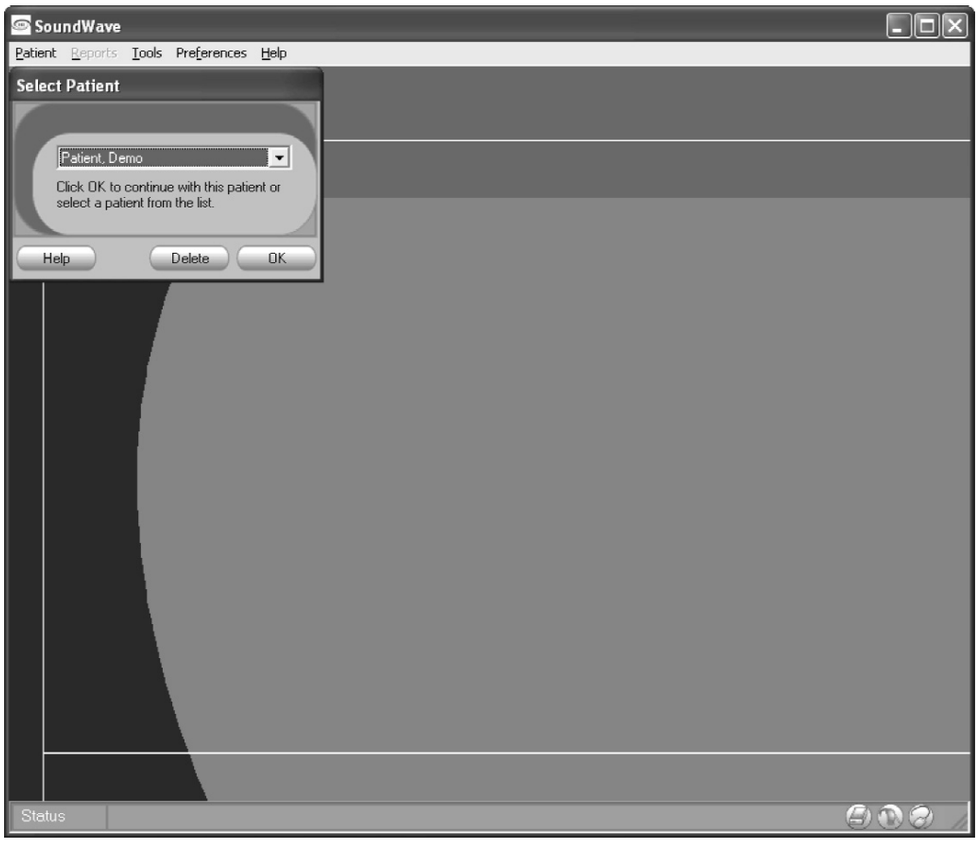
SoundWave Windows

SoundWave's Main window

The Main window displays when you first open SoundWave. It is within this window that all other SoundWave windows will display.



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Select Patient

Before you can begin using the software with your patient, you must create a patient file. The Select Patient window displays each time that you open SoundWave or when you close a patient file. This window contains a menu that lists the names of all the patients in your database, and a ***New Patient*** option.

Reading the Patient's Name from the Processor

Whether you are creating a new patient file or opening an existing file, the steps are essentially the same. SoundWave automatically detects when a sound processor is connected and reads the patient name. If the menu displays a patient name, then you know that it is the name on the processor. If the menu displays ***New Patient***, you know that there is no name on the processor, in other words, that the processor has not been assigned to a patient or the processor was not programmed in SoundWave.

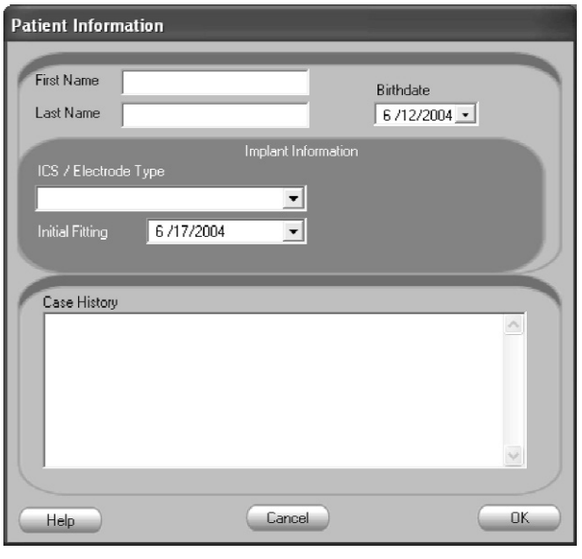
Note: ***SoundWave needs a few seconds to detect the processor and recognize the patient's name. You will know that this process is complete when the status bar displays the sound processor icon green. It is best to wait until you see the sound processor status change to green before you continue.***

SoundWave does not force you to continue with the patient that it reads from the processor. In some cases you might want to select a different patient name, for example if the connected processor is a loaner that you want to re-assign to a different patient.

Entering Patient Information

Each time you create a new patient file, you must provide certain information about that patient to the software. You will use the Patient Information window to enter this information. When you create a new patient, the software will display this window automatically, but you can return to and add or edit the patient's information any time.

If you want to add or modify the information that you entered when a patient file was created, you can access the Patient Information window from the Patient menu. Clicking on the Information option displays the Patient Information window.



Deleting a Patient

You can delete a patient from your database using the Select Patient window. When a patient name is highlighted in the menu, the Delete Button becomes active. Clicking on the Delete button will delete the patient's file. SoundWave will automatically create a backup of the patient file and store it in c:\Program Files\Advanced Bionics\SoundWave\Data before it is deleted, so that data can be recovered if needed. You will use the Import option located in the Patient menu to restore a deleted patient file.

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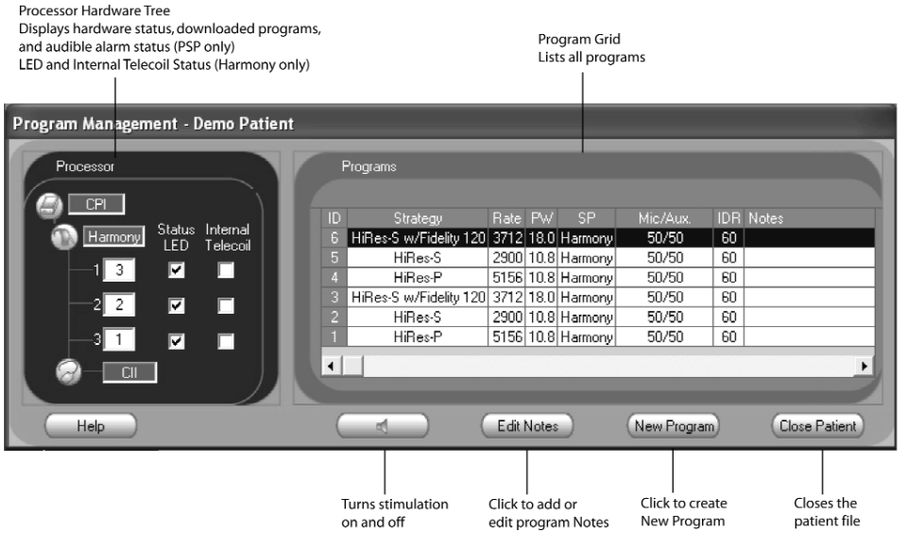
The Program Management Window

The Program Management window displays each time you open a patient's file and remains open until you close the patient's file.


Processor Hardware Tree
Displays hardware status, downloaded programs, and audible alarm status (PSP only)
LED and Internal Telecoil Status (Harmony only)
Program Grid
Lists all programs
Program Management - Demo Patient
Processor
CPI
Harmony
Status LED
Internal Telecoil
1 3
2 2
3 1
CII
Programs
ID Strategy Rate PW SP Mic/Aux. IDR Notes
6 HiRes-S w/Fidelity 120 3712 18.0 Harmony 50/50 60
5 HiRes-S 2900 10.8 Harmony 50/50 60
4 HiRes-P 5156 10.8 Harmony 50/50 60
3 HiRes-S w/Fidelity 120 3712 18.0 Harmony 50/50 60
2 HiRes-S 2900 10.8 Harmony 50/50 60
1 HiRes-P 5156 10.8 Harmony 50/50 60
Help
Edit Notes
New Program
Close Patient
Turns stimulation on and off
Click to add or edit program Notes
Click to create New Program
Closes the patient file

The Program Management window allows you to:

- View and open programs that have been created for your patient
- "TalkOver"
- Compare programs
- Edit program notes
- Indicate a program for which you want to view or print a report
- Download programs to the processor, and enable alarms, LED and Internal Telecoil (if applicable)
- Close a patient file
- Hide Programs from view

The Program Management window is divided into two panes:

- Processor Hardware Tree
- Program Grid

Processor Hardware Tree

The processor area includes the hardware tree, which displays the current status of the hardware and indicates what programs and alarms are active on the connected processor. This is where you will download programs to the processor, activate audible alarms for the PSP, and the LED or Internal Telecoil for the Harmony.

NOTE: The LED on the PSP or FireFly on the Auria BTE do not require setting. These will automatically indicate program selection, communication status and battery status.

Program Grid

The program grid displays the programs that have been created for your patient. Each row represents a single program. Clicking once on a program highlights that row. Double-clicking on the program opens a read-only version of the program. You can adjust the width of any of the columns in the grid. When you want to compare a program, edit notes of a program, or generate a report for a program you will click on it once to highlight it.

When you want to keep a program from displaying in the Program Grid, you will highlight the program and then choose ***Hide Programs*** from the Patient menu. Programs can be hidden but not deleted.

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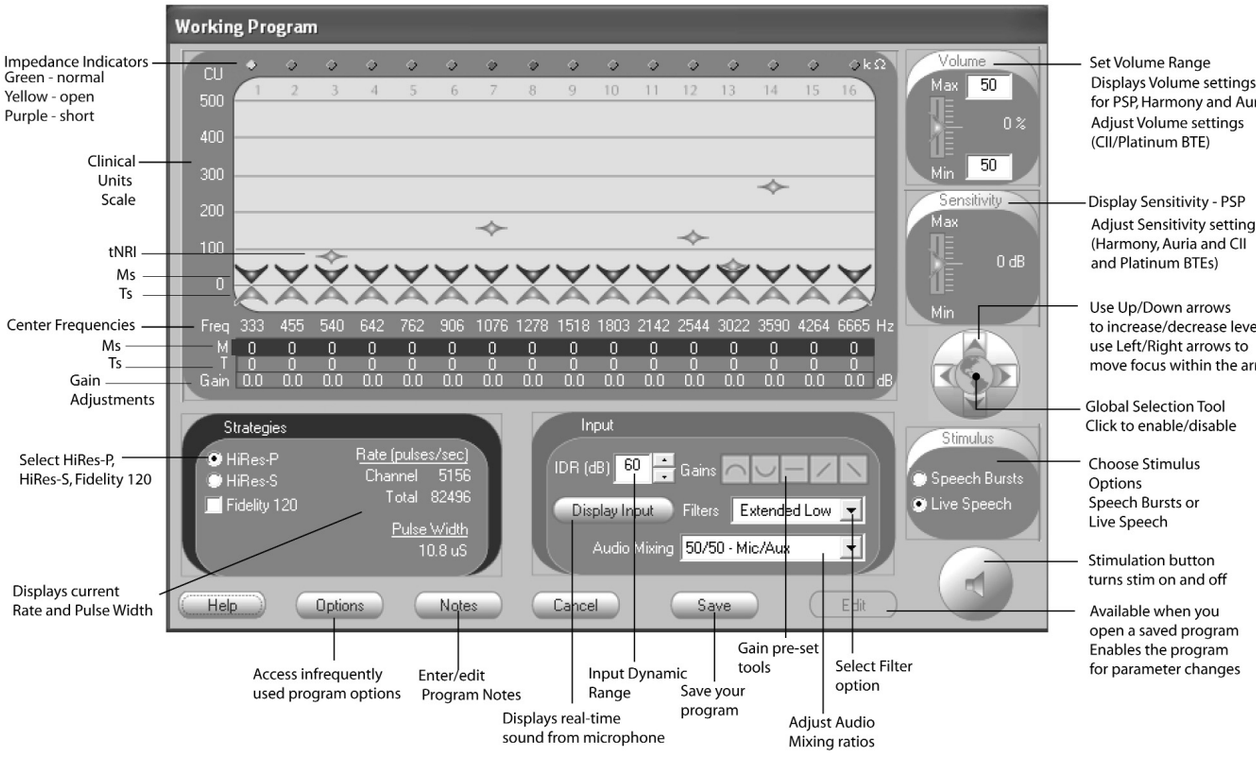
The Program Window

The SoundWave Program Window allows you to customize a program for your patient. All the most frequently used parameters are on this screen and available at your fingertips. You can create new programs from scratch or base them on existing programs.



Impedance Indicators

The Impedance indicators display on the program screen at the top of each electrode. The color of the indicator provides status information based upon the latest impedance measurement. Green indicates an impedance within normal range (1-30 kΩ). Yellow indicates an impedance outside of normal range. Purple indicates a shorted electrode. SoundWave displays a tool tip when you place the cursor over an impedance indicator.

Clinical Units Scale

The Clinical Units (CU) scale displays to the left of the electrode grid. The initial scale that displays by default is 0-500, but the actual scale is 0-6000. As Ms are increased above 500 the scale changes to 0-1000, then 0-2000 until the maximum range (0-6000) is reached. Clinical Units are also referred to as "Charge Units" in SoundWave.

Speech Bursts™

Ms are banded in groups of 4 when an even number of electrodes are active or 3 when an odd number of electrodes are active. You will use the keyboard or the level adjuster on the program window to increase or decrease Ms. As mentioned earlier, because of the Auto-T feature, Ts will adjust as you adjust Ms and remain at 10% of the M value. The selected group of Ms are indicated by both their color (blue) and the vertical lines that separate them from unselected Ms.

Strategies

SoundWave supports HiResolution strategies. HiRes-P stimulates two electrodes simultaneously (paired). HiRes-S stimulates each electrode sequentially. For both HiRes-P and HiRes-S you can select Fidelity 120 to provide 120 spectral bands. CIS and MPS can also be emulated in SoundWave if needed.

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Rate and Pulse Width

Rate and Pulse Width display the real-time values as the program fitting progresses. Rate is defined in the following table.

Table 10: Functional Description of Rate

Parameter	Description
Channel	Pulses per second per channel.
Total	The accumulated pulses per second across the entire array.

Pulse width indicates the duration of one phase of the biphasic waveform. Pulse width is kept equivalent across all electrodes. See the Options section of this manual for more details.

Audio Mixing Ratios

Audio Mixing ratios control the ratio of the sound received from the microphone and the auxiliary connection. It allows the processor microphone to remain active when connected to an auxiliary input, so patients can hear their own voices in addition to the auxiliary device (Internal Telecoil, FM system, External T-Coil, CD player, etc). All processors supporting the HiResolution Bionic Ear System (Harmony, Auria, PSP, and BTE) offer Audio Mixing ratio capability. The default for this parameter is 50/50 or accepting equivalent input from the auxiliary device and the system microphone. You have the option of adjusting the mixing ratios for individual preferences. Note: the T-Mic acts as an auxiliary microphone.

Table 11: Audio Mixing Ratios and their Applications

Audio Mixing Ratio	Description	Processor Mic	Auxiliary Input
Processor Microphone + Auxiliary Input 50/50 Mix (50/50 - Mic/Aux)	Equal mix of each input. A 50/50 does not imply that each signal has been reduced by half.	On	On
Processor Microphone + Auxiliary Input 30/70 Mix (30/70 - Mic/Aux)	With this option, different amounts of gain are applied to the two signals. Less gain is applied to the signal pathway from the processor microphone so that the input for the auxiliary device is emphasized. Remember that sound input to the processor microphone will be reduced using this program, even when disconnected from auxiliary input.	On attenuated by -10 dB	On
Processor Microphone only (Mic Only)	With this option, no gain is applied to the input from the auxiliary audio-device. Only the processor microphone will be active even when coupled to the auxiliary device.	On	Off
Auxiliary Input only (Aux Only)	This option would be appropriate when the listener wants to hear only the signal from the audio-device such as a T-Mic, CD player, cell phone or stereo. The processor microphone is completely de-activated. This programming option assumes that the end user has an appropriately attenuated and qualified patch cable if applicable. Even when an aux device is not connected, the processor microphone remains off.	Off	On
Auxiliary input only attenuated (Aux Only (Atten.))	The listener wants to hear only the signal from a commercially available audio-device and has obtained an "off the shelf" patch cable, which has not been tested with the sound processor. However the signal level emanating from the audio-appliance is quite high and even with the volume on that device and on the processor turned to a minimum setting the signal is too loud for the user. The –20 dB attenuation applied to the audio-input signal will allow the user to set the volume of the audio-appliance and the processor to a more appropriate setting.	Off	On attenuated by -20 dB

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Filters

This option allows you to select between Extended Low (default, sets to 250Hz) and Standard Filters (sets to 350Hz).

Display Input

This feature allows you to view the real-time input and see the shape of any gains applied to the input. When stimulation is on, you can view the characteristics of the input sound across all channels.

Input Dynamic Range

Input Dynamic Range (IDR) defines the amount of acoustic input that is mapped into the patient's electrical dynamic range. IDR determines the intensity range (width) captured by the processor for input signals. The HiResolution Bionic Ear System has the capability to capture a very wide IDR of up to 80 dB. The default setting is 60 dB.

Stimulus Options

There are two stimulus options available by default on the Program window: Speech Bursts and Live Speech. You can set Ms with either option. Tone Bursts are also available but must be enabled from the program's Options window. Speech and Tone Bursts are not available for stimulation when creating Fidelity 120 programs.

Global Selection Tool

The Global Selection Tool allows you to globally adjust M or Ts. When the tool is active, only global selection is allowed. You must deselect when you want to make adjustments to M, T, gain, or clipping on an individual electrode.

Table 12: Functional Description of Global Selection Tool by Stimulus Option

Stimulus	Global Selection Tool State	Ms	Ts	Gains
Live Speech	Enabled	All Ms are selected. Clicking on a single M is not possible.	Not selectable unless Manual Ts is selected in program Options, then All Ts are selected.	Unable to set individual gains. Gain profiles available.
	Disabled	Single M selection is allowed.	Not selectable unless Manual Ts is selected in program Options, then single T selection is allowed.	Able to set individual electrode gain.
Speech Burst	Disabled	Ms are selected in groups of 4 or 3 depending upon the number of active electrodes.	Not selectable.	No gain setting permitted.
Tone Bursts	Disabled	Single M selection only.	Not selectable unless Manual Ts is selected in program Options.	No gain setting permitted.

Level Adjuster

The Level Adjuster tool consists of the four arrows surrounding the Global Selection Tool. The Level Adjusters are the functional equivalent of the arrow keys on your keyboard. Using the up and down arrows, you can increase or decrease M, Ts or gains. Using the left or right arrows, you can move across the array.

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Volume and Sensitivity

The Volume and Sensitivity fields allow you to view or adjust the current settings depending upon which processor type is connected. You can also set both the maximum and minimum setting for volume range. Most patients don't need more than a +50% range.

The following table summarizes the control dependency of the visual display in SoundWave. Hardware Control indicates the ability of SoundWave to display the current position of the control on the processor. Changing the position of the slider is not possible with the mouse or keyboard. Software Control indicates the ability for you to change the setting in real-time using the volume and sensitivity sliders. You can manipulate the volume and sensitivity sliders using the mouse or keyboard.

Table 13: Functional Description of Volume and Sensitivity Control by Processor

Processor	Volume Setting	Sensitivity Setting
Harmony and Auria	**Hardware control**. Visual display reflects real-time changes of the volume dial on the patient's processor.	**Software control**. SoundWave sliders control setting in real-time). Value that is set when program is saved becomes that program's sensitivity setting.
CII and Platinum BTE	**Software control**. SoundWave sliders control setting in real-time ***Note: Stimulus must be set to Live Speech to adjust volume with the slider.)*** **Hardware control** Visual display reflects real-time changes of the volume dial on the patient's processor.	**Software control.** SoundWave sliders control setting in real-time. Value that is set when program is saved becomes that program's sensitivity setting.
PSP	**Hardware control**. Visual display reflects real-time changes of the volume dial on the patient's processor.	**Hardware control.** Visual display reflects real-time changes of the volume dial on the patient's processor.

Stimulation Button

This button allows you to turn stimulation on and off. You can also use the "s" key on the keyboard to start stimulation. The space bar will always stop stimulation.

Edit Button

The Edit button is enabled when you open an existing program window. Programs display in read-only and you will be unable to change any of the parameters until you click on the Edit button.

Notes Button

The Notes button allows you to enter or edit program notes. These notes become part of the program and display on the Program Details and the Visit History reports. Notes can also be entered or edited from the Program Management window.

Cancel Button

The Cancel button closes the Program window and discards any parameter changes that have been made.

Save Button

The Save button closes the Program window and saves all program parameters to the database.

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Options Button

The Options button brings up a window that contains the less frequently used program parameters and settings.

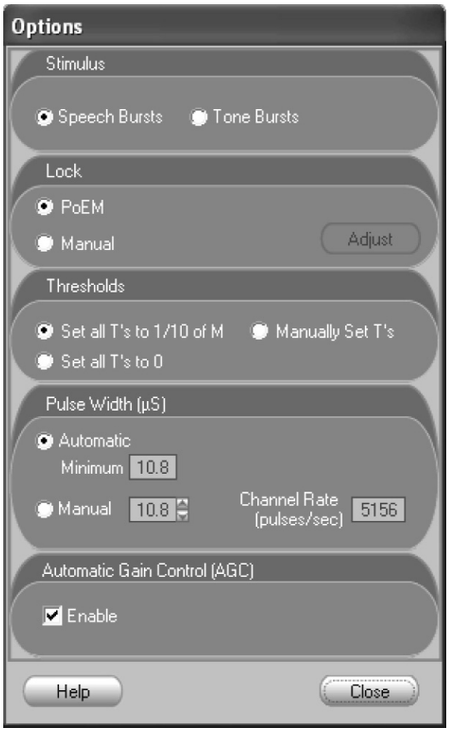
Stimulus

Select Speech Bursts (default) or Tone Bursts. Selecting Tone Bursts allows for single electrode tone stimulation. This setting controls which of these options is available for selection in the Program window.

Lock

PoEM – Power Estimator automatically adjusts RF in real time providing just the right amount of power for every environment. PoEM is the default setting.

Manual Lock Adjustment – Contact Advanced Bionics Corporation for assistance.



Thresholds

10% M is the default.

In order to adjust Ts, you must select the Manually Set Ts option first, and then adjust using the arrow keys. You can adjust Ts globally or on an electrode-by-electrode basis when in Live Speech.

You can also Set All Ts to 0.

Changing the Manually Set T option (e.g., Set all Ts to 10% of M, or Set all Ts to 0) after manually obtaining Thresholds will cause SoundWave to discard the manual levels. If you have measured Ts manually, and want to insure that the manual levels are saved, save the program before making a different Threshold selection.

Pulse Width

Automatic is the default. Automatically adjusts pulse width as needed.

You may choose to adjust pulse width manually, by clicking on the Manual option button. You can only adjust manually with stimulation off and it is a global adjustment. Level increases in .9 increments and does not require re-measurement due to constant charge. If you select the Manual option the system no longer calculates compliance.

Automatic Gain Control

Automatic Gain Control (AGC) is enabled by default. AGC automatically optimizes gain and compression to the listening environment. To disable uncheck the box. Disabling AGC results in peak clipping and may be situationally preferred by some listeners.

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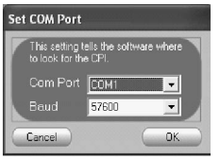
Preferences in SoundWave

The Preference menu allows you to set application specific parameters. You can set preferences for communication with the CPI, showing or hiding tNRI in the program window, or enabling the Internal Telecoil to allow customization of parameters for a program that will utilize the Harmony's Internal Telecoil capabilities.

COM Port

During start up, SoundWave locates the CPI connected to your COM Port. If you need to change the COM Port or the communication speed, you can do so from SoundWave's Preferences menu. Typically, it will not be necessary for you to change these settings.

1. From the Preference menu, click on the Com Port option.
   SoundWave displays the following window.



2. Select the desired COM Port and the Baud rate.

Note: ***When changing the communication speed in SoundWave, you may also need to change the Baud Rate settings using the Hardware Management tool located in the Windows Control Panel. Contact Advanced Bionics for support if needed.***

3. Click on ***OK***.

Display tNRI

This menu option allows you to toggle on/off the tNRI markers that display on the program window. If you have selected tNRI levels to display (See the section on the NRI Management window in the NRI chapter for details on this procedure) a checkmark next to this menu option indicates tNRI values display on the program window; no checkmark indicates tNRI values are hidden. This selection will apply to all patient files in your SoundWave database.

Enable Harmony Internal Telecoil

This menu option allows you to assess the internal telecoil of the Harmony BTE during a programming session, without enabling the internal telecoil on the processor. You can then make appropriate adjustments in real-time from the Program window, or compare programs from the Program Management window.

When you close the patient file, SoundWave disables the Enable Harmony Telecoil setting. The next time you open a patient file and want to assess the telecoil during programming, you must first enable this feature in the Preferences menu.

Disabling this function disallows the assessment of the Internal Telecoil during a programming session, but does not preclude you from enabling the internal telecoil on the processor.

Note: ***Enabling the Internal Telecoil for any given program slot will automatically disable the LED status indicator from that program.***

It is important to note that a downloaded program must have an auxiliary input setting in order for the internal Telecoil to be enabled AND you MUST select the program slot checkbox on the Program Management window for the parameter to be downloaded to the processor. Without these important steps, the internal telecoil WILL NOT FUNCTION when the processor is disconnected from the system.

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Fitting with SoundWave

The first step for any fitting is to open the patient's file. At an initial fitting you will also want to initialize the processor and run Electrode Conditioning.

Creating a Patient File

1. Launch the SoundWave application. (Double-click on the SoundWave icon on the desktop).
   The software displays the Select Patient window, detects the sound processor, reads the patient name if available.

   If a patient name exists on the processor, SoundWave displays that name in the menu on the Select Patient window. If no name was available, it displays New Patient.

2. Select ***New Patient***.

3. Click on ***OK***.
   The software displays the Patient Information window.

4. Enter all information and click on the ***OK*** button.
   SoundWave displays the Program Management window and the Associate Implant with Patient File message.

Associating the Implant with a Patient's File - IntelliLink™

SoundWave includes the capability to limit stimulation to a particular implant. SoundWave reads the unique serial number directly from the implant and associates that number with a particular patient. When this feature is active, programs downloaded to a processor will not stimulate any patient other than the one to which it is associated. This feature provides an important safety measure, and although it can be disabled, we recommend that you take advantage of this proprietary feature. Each time you create a new patient, SoundWave displays a prompt to associate the implant with the open patient file.

SoundWave
Patient Reports Tools Preferences Help
Program Management - Demo Patient
Processor
CPI
Harmony
Status LED
Internal Telecoil
1
2
3
CII
Help
Programs
ID Strategy Rate PW SP Mic/Aux. IDR Notes
Close Patient
Associate Implant With Patient File
The open patient file does not have an implant associated with it.
Would you like to associate the connected implant with this patient file?
Yes: Associate connected patient's implant with this patient file. Programs downloaded to a processor from this file will only stimulate this patient's implant.
No: Do not associate connected implant with this patient file. Programs downloaded to a processor will stimulate any patient's implant.
Help
No
Yes
Status

You can disassociate the implant using the Tools menu. We DO NOT recommend that you disassociate an implant unless instructed to do so by Advanced Bionics personnel.

1. When SoundWave displays the ***Associate with Patient File*** prompt, click on the ***Yes*** button.
   SoundWave makes the association and initiates impedance measurement. The ICS icons in the hardware tree display green.

Note: ***If you answer No to this prompt, the implant icons in the Hardware Tree and Status bar display yellow. Although you can stimulate in this condition, you will be unable to measure Impedances manually or automatically.***

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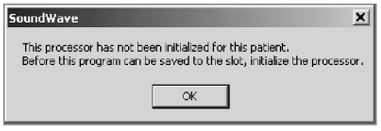
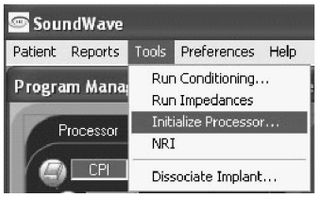
Initializing the Sound Processor

You must initialize the processor to assign it to a patient. It is for this reason that we recommend that you initialize after you have opened a patient file, but before you begin the fitting. Although SoundWave allows you to initialize at anytime during a fitting session, it will not let you download programs to the processor until you initialize. SoundWave prompts you to initialize if you have not done so, when you attempt to download programs to the processor. Remember, when you initialize, it erases all information from the processor.

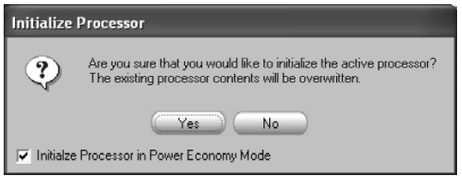

SoundWave
This processor has not been initialized for this patient.
Before this program can be saved to the slot, initialize the processor.
OK

1. Click on the ***Tools*** menu.
   The software displays the Tools menu options.



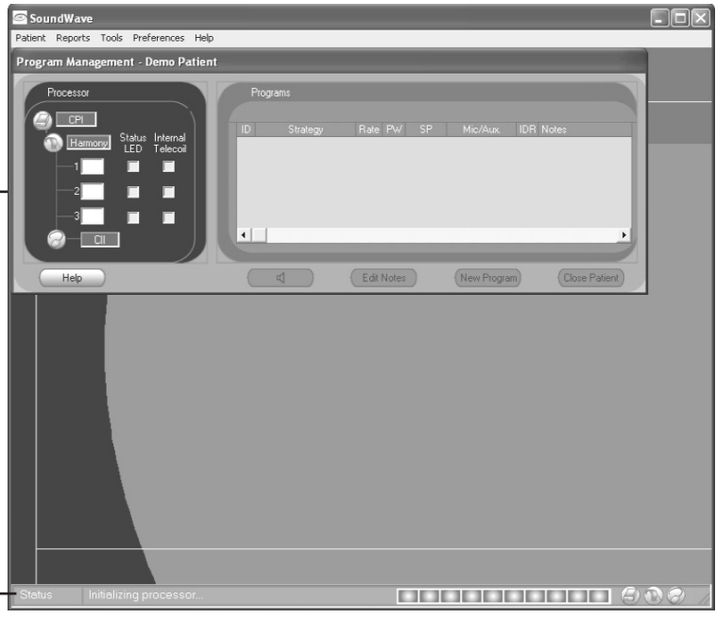
Note: ***If you want to completely "blank out" a processor, you can initialize it without a patient file open.***

2. Click on ***Initialize Processor***.
   The software displays the following message.


Initialize Processor
Are you sure that you would like to initialize the active processor?
The existing processor contents will be overwritten.
Yes
No
Initialze Processor in Power Economy Mode

Power Economy Mode (Harmony only)
Power Economy Mode provides a significant increase in battery life. This option is the default setting. Only deactivate if you have difficulty maintaining lock during programming. This selection applies to all programs downloaded to the processor.

3. Click on ***Yes***.
   The software initializes the processor.



Hardware Tree and Status bar Icons Color-Coding
The Hardware Tree and Status bar provide visual indication when you are initializing a processor. They also indicate the status of the CPI, processor, and implant throughout the fitting process.

CPI: Green = OK
Red = no connection

SP: Green = OK
Yellow = Communication in progress
Purple = Driver download in process or Parameters being set for connected processor.
Red = No communication

ICS: Green = OK
Red = No communication
Yellow = Implant not associated with current patient

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Running Electrode Conditioning

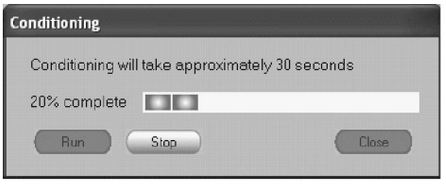
Electrode conditioning prepares the electrodes for stimulation prior to programming. The introduction of low level current removes any protein build up or air bubbles from any electrodes. Impedances are measured during the conditioning process. Electrode Conditioning is only necessary for initial fittings, or when turning on electrodes that were previously disabled. Impedances are also measured when a patient file is initially opened with the processor connected or when the processor is connected while the patient file is open.

Note: ***If the implant is not associated with the patient file, the system will not automatically measure impedances, and you will be unable to run Electrode Conditioning or manually measure impedance.***

1. From the Tools menu, click on the ***Run Conditioning*** option.
   The software displays the Conditioning dialog box

Run Electrode Conditioning for all initial fittings and when turning on electrodes that were previously disabled.

2. Click on the ***Run*** button.
   The software keeps you informed of the progress…



You can stop Electrode Conditioning by clicking on the Stop button or Space bar.

   and displays the following message when Electrode Conditioning is complete.

3. Click on ***OK***.
   SoundWave closes both the message and Electrode Conditioning windows. You are ready to begin creating programs.

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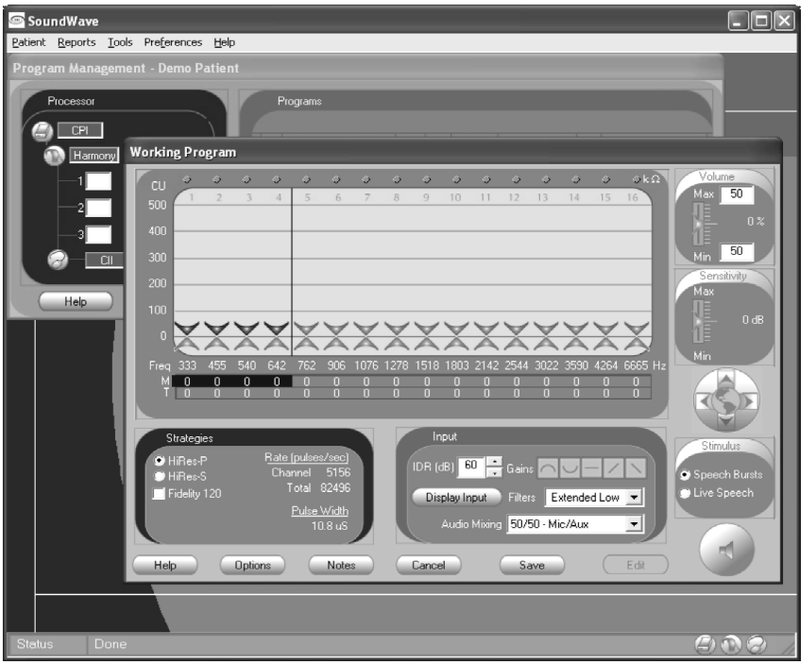
Creating a New Program

1. From the Program Management window grid, click on the ***New Program*** button.

The software displays a new program window.



The Speech Burst option is selected by default. The software highlights the first 4 Ms, indicating the electrodes where stimulation will be presented.

Note: Always work from left to right in the array or start with Live Speech.

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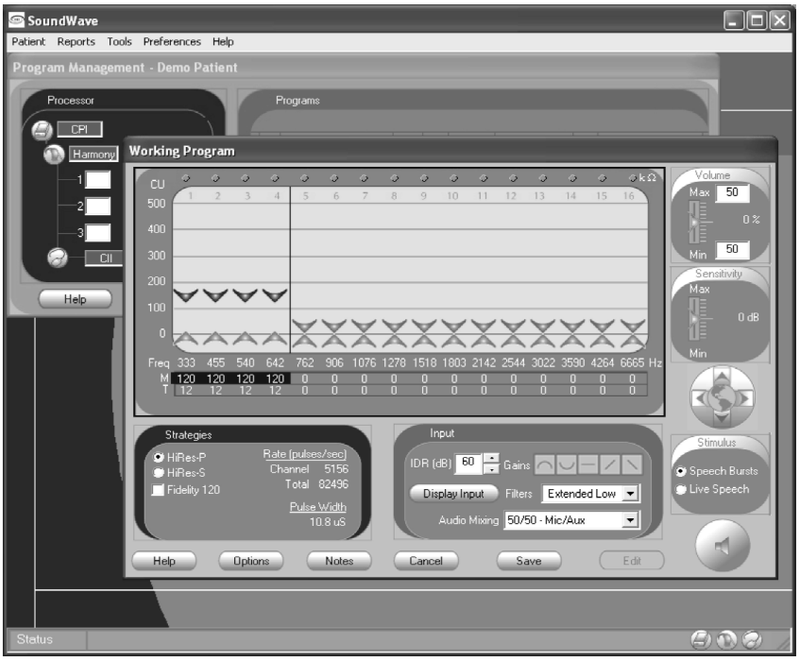
Measure M Levels with Speech Bursts



Note that as you are adjusting M, SoundWave automatically adjusts the Pulse Width and T levels.

Automatic Pulse Width
SoundWave automatically adjusts pulse width during programming to maintain fast rates at the narrowest pulse width. The algorithm takes into account each patient's unique physiology and M levels and performs all the necessary computations each time M levels are changed.

1. Turn on Stimulation using the ***Stimulation Button*** or "***s***" key.
2. Using the up arrow key on the screen or keyboard, increase the level until the patient perceives the stimulus as most comfortable.
3. Press the ***right arrow key*** on the screen or keyboard to move to the group (3 or 4 Ms) and then using the up arrow key, increase the level until the patient perceives the stimulus as most comfortable.
   Notice that as you move across the array from apex to base, two things happen.

   First, an overlap occurs as you move to the next group of Ms. When an odd # of electrodes is active, each group includes 3 Ms and only the last M of the group is included in the overlap. When an even number of electrodes is active, each group includes 4 Ms and the last 2 Ms of the group are included in the overlap. The new group consists of the last 1 or 2 Ms of the group just measured, and next two Ms in the array.

   Next, all Ms in this group adjust to a level that is 60% of the previously measured group. This allows you to start stimulation closer to where you will obtain a Most Comfortable Level instead of beginning each group at 0. This interpolation only occurs the first time you advance through the array.

The clinical unit (CU) represents constant charge. Therefore, as adjustments in pulse width are made, charge is kept constant (CU remains the same) eliminating the need to re-measure levels when pulse width is changed.

Auto-T
Auto-T refers to the automatic setting of threshold levels during programming. T levels are set at 1/10th M across each electrode. You will no longer need to set T levels on an electrode-by-electrode basis, saving time and preventing patient fatigue.

Note: ***If you have 16 active electrodes, and you don't want to use this overlap method, you can use the mouse instead of the arrow keys and click on the next set of Ms (e.g. 5-8). No interpolation takes place using this method.***

4. Press the ***right arrow key*** on the screen or keyboard and repeat stimluation for all groups of M in the array.
5. Turn off stimulation using the ***space bar*** or ***Stimulation Button***.

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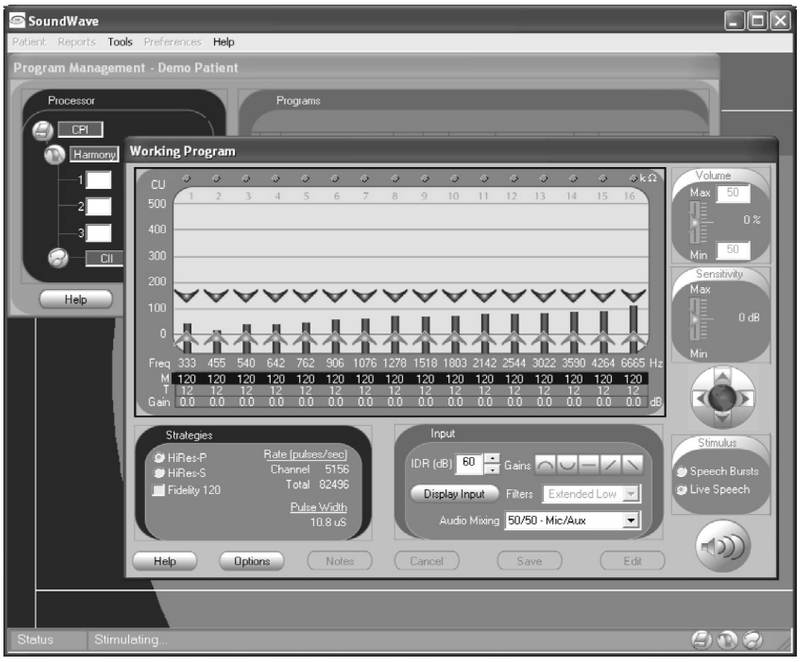
Program with Live Speech

1. Click on ***Live Speech***. Remember to set volume and sensitivity on the sound processor to suggested user settings (midpoint).
2. Turn on Stimulation using the ***Stimulation Button*** or "***s***" key.
3. Adjust Ms until patient reports a most comfortable level.
4. Turn off stimulation using the ***space bar*** or ***Stimulation Button***.
5. Click on ***Save***.



Create Fidelity 120 Program *(Harmony or PSP only)*

Fidelity 120 programs require a minimum of 3 electrode pairs. Adjacent electrodes are needed to make a pair.

1. Determine if patient has a preference for HiRes-P or HiRes-S.
2. Open the program created in the preferred strategy and select Edit.
3. Globally reduce M levels or turn down the processor volume before turning on stimulation.
4. In Live Speech, enable Fidelity 120 for the preferred strategy.
5. If patient does not have a preferred strategy, enable Fidelity 120 in HiRes-S. (The rate does not change between HiRes-S and HiRes-P for Fidelity 120).

Note: ***You can try Fidelity 120 in both HiRes-S and P as desired to determine preference***

6. Adjust M levels in Live Speech with Fidelity 120 (be sure processor volume is returned to recommended user setting).

Note: ***You can only stimulate using Live Speech with Fidelity 120. You cannot select Speech or Tone Bursts.***

7. Click on Save Program.

Volume Slider

All Processors: Visual display reflects real-time changes of the volume dial on the patient's processor. Default is 12:00

Harmony/Auria/PSP: You cannot directly interact with the volume sliders.

Sensitivity Slider

Harmony/Auria/BTE: Use the slider to set program's sensitivity. The position of the slider when the program is saved becomes the default sensitivity for that program.

The BTE toggle switch cannot be programmed to control sensitivity.

PSP: Sensitivity visual display reflects real-time changes of the sensitivity dial on the patient's processor.

Notes Button

Use the Notes button to enter program notes. You can also enter/edit notes from the Program Management window.

Making Global Electrode Adjustments

Make sure that Global Selection Tool is enabled (indicated with blue color).

Making Individual Electrode Adjustments

Make sure that Global Selection is disabled (indicated with gray color).

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Additional Fitting Tasks

Viewing/Measuring Impedances

You can view impedances from the program window. Green indicates an impedance within normal range (1-30 kΩ). Yellow indicates an impedance outside of normal range. Purple indicates a short. SoundWave displays a tool tip when you place the cursor over an impedance indicator. Mouse over the circles at the top of each electrode to view that electrode's impedance. Mouse over the kΩ label to view all impedances.

Impedances are measured automatically:

- Each time you open a patient file if you have associated implant with the patient file.
- Each time you run Electrode Conditioning.

Note: ***If the implant is not associated with the patient file, the system will not automatically measure impedances.***

Management of Shorts and Opens

SoundWave will alert you to any shorted (purple) or open (yellow) electrodes.

Open/Short Notification
At least one open (yellow) or shorted (purple) electrode has been detected. Please refer to the Help file for fitting recommendations as needed.
OK

You can disable or enable these electrodes in a program. Control measures designed into the SoundWave fitting system ensure safe use of programs with enabled open and or shorted electrodes, although patient perception of sound quality may vary.

Therefore Advanced Bionics recommends disabling shorted and open electrodes, particularly for children. If shorted or open electrodes are detected after a period of device use, recipients may report a preference for programs with these electrodes enabled. However, we do recommend that patients try a program with these electrodes disabled to determine if a preference or performance difference is observed after a period of adjustment.

Clinician Initiated Impedance Measurement

You can measure Impedances manually anytime you wish provided that the implant has been associated with the patient.

1. Click on the ***Tools*** menu, and then click on the ***Run Impedances*** option.
   SoundWave measures impedances and displays the progress in the status bar at the bottom of the main SoundWave window.

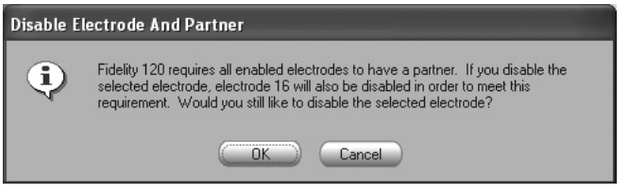
Enabling/Disabling an Electrode

You may occasionally find it necessary to disable an electrode, for example, in the case of extra-cochlear electrodes, a somatic response or quality issues.

Note: ***Fidelity 120 requires electrodes to function as electrode pairs. When you attempt to disable an electrode in a Fidelity 120 program that will leave an electrode without a partner, SoundWave will display a message. You must decide to disable both electrodes in the pair, or leave both electrodes enabled. Fidelity 120 requires a minimum of 3 enabled electrode pairs.***

Disabling an electrode

1. From the program window, right-click on an electrode.
   SoundWave displays a pop up menu.
2. Click on the ***Disable Electrode*** option.
   SoundWave grays out the electrode background. For Fidelity 120 programs, SoundWave may display the following message, indicating which electrode must be disabled in addition to the one you selected.


Disable Electrode And Partner
Fidelity 120 requires all enabled electrodes to have a partner. If you disable the selected electrode, electrode 16 will also be disabled in order to meet this requirement. Would you still like to disable the selected electrode?
OK
Cancel

3. Click ***OK*** to disable both the selected electrode and its partner .
   Click ***Cancel*** to leave both electrodes enabled.

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Enabling an electrode

1. From the program window, right-click on an electrode.
   SoundWave displays a pop up menu.
2. Click on the ***Enable Electrode*** option.
   SoundWave turns on the electrode.

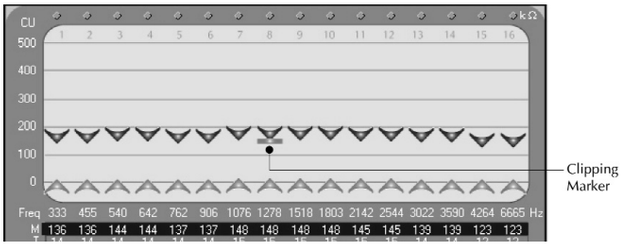
Setting Clipping

If you need to prevent stimulation from exceeding a certain level, such as to prevent a non-auditory response, you can enable clipping on a single electrode or on multiple electrodes.

Clipping is accessed by right-clicking on an electrode. Clipping can be enabled when the program is in Live Speech or Speech Bursts stimulation modes, but can only be adjusted from its default value (M) in Live Speech.

Enabling Clipping

1. From the program window, right-click on an electrode.
   SoundWave displays a pop up menu.
2. Click on the ***Enable Clipping*** option.
   SoundWave displays the clipping marker at M.



Changing the Clipping Level

1. Make sure that ***Live Speech*** is selected.
2. Click on the ***Global Selection*** tool to disable it.
   The tool changes from blue to gray.
3. Click on the ***clipping marker***.
4. Increase or decrease the level at which clipping occurs using the up or down arrow keys on the screen or keyboard.

Disabling Clipping

1. From the program window, right-click on an electrode.
   SoundWave displays a pop up menu.
2. Click on the ***Disable Clipping*** option.
   SoundWave removes the clipping marker.

Setting Volume Range

You can type in a maximum and minimum setting for volume range, or you can use the volume control in conjunction with your patient's feedback to identify the maximum or minimum levels. Most patients don't need more than a ±50% volume range.

Setting Range Limits using the Volume Control — Maximum Level

1. Verify sensitivity is set to the midpoint (12 o'clock).
2. With Live Speech on, adjust the volume control to the level that the patient indicates is the loudest level tolerable.
   Note the % value. This is the percentage of the dynamic range.
3. Type that value (1-100) in the Maximum text field and press the Enter key.

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Setting Range Limits using the Volume Control — Minimum Level

1. With Live Speech on, adjust the volume control to the level that the patient indicates is the softest level tolerable.
2. Note the % value. This is the percentage of the dynamic range.
3. Type that value (1-100) in the Minimum text field and press the Enter key .

Note: It is not necessary to type a minus sign.

To Disable Volume Control

SoundWave allows you to completely disable the processor Volume Dial. With the following settings the volume remains at a fixed level (Most Comfortable) and CANNOT be changed using the Volume Dial.

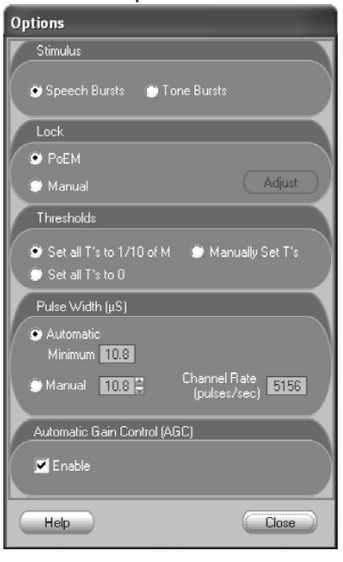
1. Type 0 in both Maximum and Minimum text fields.

Sweep/Balance

In SoundWave, balancing with Speech Bursts is done by manually toggling between groups of electrodes. This allows you to balance at levels equivalent or close to Live Speech M. Alternatively, you can balance with tone bursts across all sixteen electrodes. However, tone bursts of very narrow pulse width have very poor correlations with Live Speech stimulation levels. Therefore you may not be able to balance at M with single electrode stimulation. Alternatively, you can increase the pulse width for the tone burst to balance, then return to a narrow pulse width (given constant charge) for Live Speech.

Setting Ms using Tone Bursts

1. From the Options window, click on the ***Tone Bursts*** option button that displays in the area labeled Stimulus.



*In the Stimulus field, click on **Tone Burst** option if you want to set Ms or balance using Tone Bursts.*

*In the Pulse Width field, click **Manual** if you want to increase pulse width to balance or sweep with Tone Bursts.*

2. Return to the program window. Ms are now individually selectable.
3. Turn on Stimulation.
   The system presents Tone Bursts on the selected electrode.

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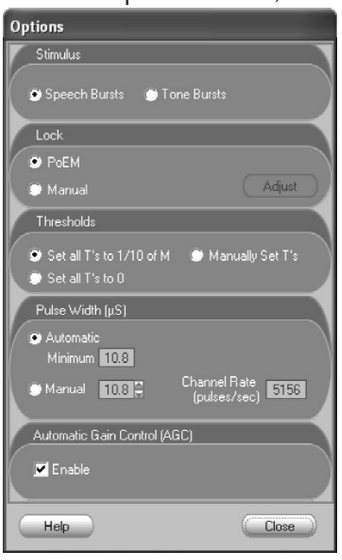
Manually Setting Ts

SoundWave automatically adjust Ts to 10% of M levels. After measuring Ms, you may want to adjust Ts manually to help troubleshoot an unwanted percept. You can use Live Speech or Tone Bursts to set Ts. You CANNOT use Speech Bursts to set Ts. You can adjust Ts globally, or by individual electrode.

Manually Adjust Ts

1. Click on the ***Options*** button in the Program window.
2. From the Options window, click on the ***Manually Set Ts*** option button that displays in the area labeled Thresholds.



In the Stimulus field, click on ***Tone Burst*** *option if you want to use Tone stimulation to manually adjust individual Ts.*

In the Stimulus field, click ***Manually Set Ts*** *if you want to troubleshoot after setting Ms.*

2. Click on ***Close***.

Manually Adjust Ts globally

1. From the Program window, click on ***Live Speech*** and on any T.
   SoundWave highlights all Ts.
2. Use the arrows on the keyboard or screen to increase or decrease levels.
   SoundWave adjusts all Ts.

Note: If you change the Threshold option back to 10% or the other option, which is setting all Ts to 0, any manual levels that you obtained will not be remembered by SoundWave.

Manually Adjust Ts Electrode-by-electrode

1. From the Program window, click that the Global Selection tool is not enabled (gray).

2. Click on any T and use the arrows on the keyboard or screen to increase or decrease levels.
   SoundWave highlights the T and adjusts only that T.

Note: Changing the Manually Set T option (e.g., Set all Ts to 10% of M, or Set all Ts to 0) after manually obtaining Thresholds will cause SoundWave to discard the manual levels. If you have measured Ts manually, and want to insure that the manual levels are saved, save the program before making a different Threshold selection.

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Adjusting Gains

You can adjust gains on an individual electrode or on a global basis. Gain is applied to the input signal.

Adjust Gains Globally

1. From the program window, verify that the ***Live Speech*** option is active; otherwise, click on Live Speech.
2. Click on the Gain profiles to globally change levels.

Adjust Gains on Individual Electrodes

1. From the program window, click on the ***Live Speech*** option.
2. Click on the ***Global Selection*** tool to disable it.
   The tool changes from blue to gray.
3. Click on the ***numeric Gain value*** at the bottom of the electrode.
   SoundWave highlights the gain level.
4. Use the up and down arrow keys on the screen or keyboard to adjust the level up or down.

Assessing Harmony's Internal Telecoil during a Programming Session

Enabling a program to utilize the Internal Telecoil on the Harmony Processor is done on the Program Management screen. However, you can assess and make changes to programs using the Internal Telecoil using Live Speech during a programming session.

1. Click on the ***Preferences*** menu.
2. Click on the ***Enable Harmony Telecoil*** option.
   A check indicates the option is active.
3. From the Program window, turn on Live Speech stimulation and adjust program as desired.

Note: ***Disable this option if you are not assessing a program for use with the Telecoil. Failure to do so could cause noise to be present in programs not utilizing the Internal Telecoil during the fitting session.***

You may also compare programs from the Program Management screen to make assessments using the Telecoil.

When you close a Patient File, the Enable Harmony Telecoil option is automatically reset to Disabled.

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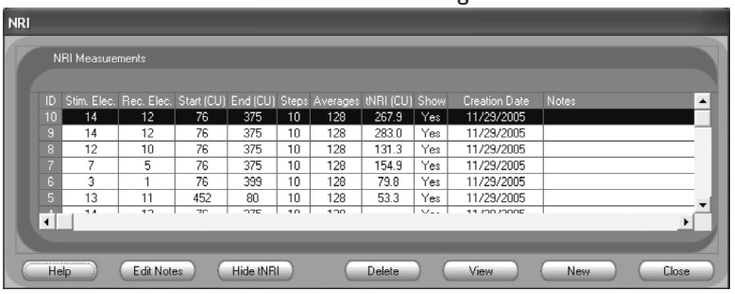
Displaying tNRI values in the Program window

SoundWave allows you to display the patient's measured tNRI values in the program window. The setting in the ***Show*** column of the NRI Management window determines whether or not tNRI markers will display in the program window. The setting defaults to "Yes", which indicates that the tNRI value will display in the program window. Changing this setting to "No" precludes tNRI values from displaying in the program window. It is possible that more than one tNRI value may be available from the same electrode; only the most recent tNRI value for each electrode displays in the program window.

Hiding tNRI levels

You will use this option to prevent the highlighted tNRI value from displaying in the patient's program window.

1. From the NRI Management window, highlight the row whose values that you do NOT want to display in the program window for your patient.
2. Click on the ***Hide tNRI*** button located along the bottom of the window.

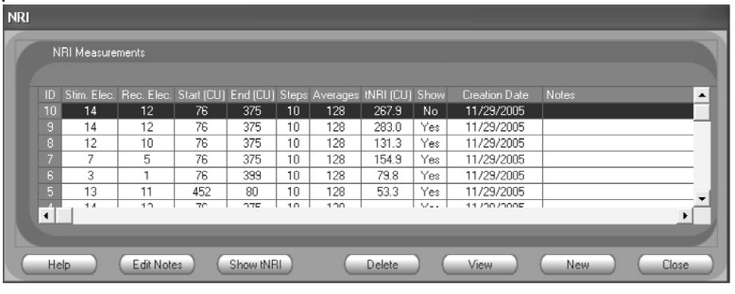


The system displays No in the Show column for the highlighted row and the button label changes to Show tNRI.

Note: ***The Display tNRI option in the Preference menu controls whether the tNRI values that you select here in the the NRI Management window, display on the Program window. This option is enabled by default. If your markers fail to display in the Program window, check to make sure this option is enabled in the Preference menu.***

Showing tNRI levels

1. Use the NRI utility to establish tNRI values on desired electrodes.
2. From the NRI Management window, highlight the row whose values you want to display in the program window for your patient.



3. Click on the ***Show tNRI*** button located along the bottom of the window.
   *The system displays **Yes** in the Show column and the button label changes to Hide tNRI.*

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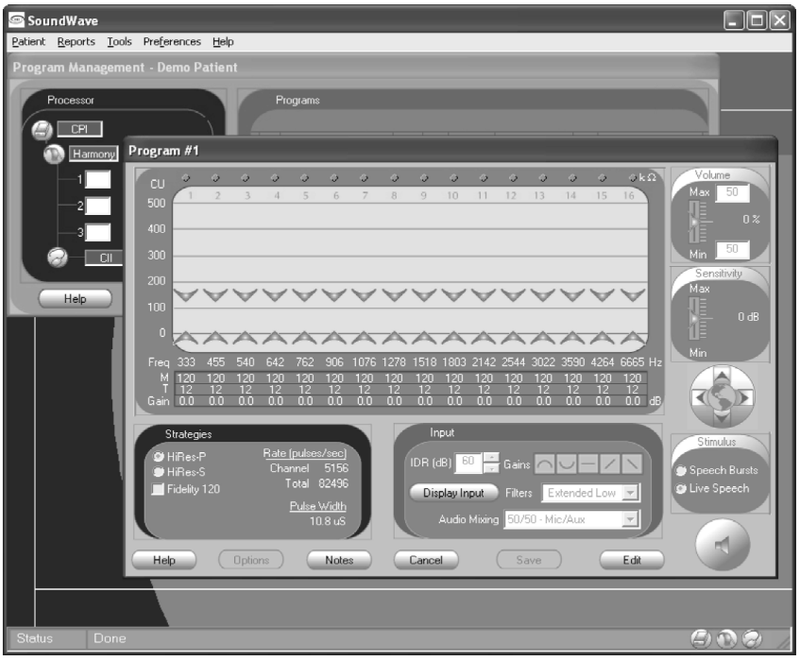
Editing an Existing Program

Once you have created a single program, typically, you will use that program as the basis for subsequent programs.

1. From the Program Management window, double-click on the program upon which you want to base your new program.
   The software displays that program. You may view the details of that program but may not change anything. If you choose to Edit the program, you will have to save it as a new program.



You can globally adjust Ms and Ts and Gains when in Live Speech. For Ms and Ts, you must enable the Global Selection Tool. It is active by default when you select Live Speech.

When the tool is active, all the levels highlight (blue). The tool is active by default when you click on the Live Speech option button. If you want to adjust an individual electrode, you must de-activate Global Selection.

You can only adjust Gains globally in Live Speech using the Gain profiles. You adjust individual electrode gains by de-activating the Global Selection, clicking on the gain level at the bottom of the electrode and then using the up or down arrows keys on-screen or the keyboard.

2. Click on the ***Edit*** button.
   The software activates the program for editing. Notice that the Edit button is now grayed out.
3. Make changes as you wish.
4. Click on the ***Save*** button.

Create a Fidelity 120 Program *(Harmony or PSP only)*

1. Open the program created in the preferred strategy and select Edit.
2. Globally reduce M levels or turn down the processor volume before turning on stimulation.
3. In Live Speech, enable Fidelity 120 for the preferred strategy.
4. If patient does not have a preferred strategy, enable Fidelity 120 in HiRes-S. The rate does not change between HiRes-S and HiRes-P for Fidelity 120.
5. Adjust M levels in Live Speech with Fidelity 120 (be sure processor volume dial is returned to midpoint setting).
6. Click on Save Program.

Note for Fidelity 120 Programs:
Only Live Speech stimulation is available for programming Fidelity 120.

Fidelity 120 programs require a minimum of 3 electrode pairs. Two enabled electrodes must be adjacent to form a pair.

SoundWave will not allow you to leave an electrode without a partner enabled. If you attempt to disable an electrode that would result in an electrode without a partner SoundWave will give you the choice to disable both electrodes in the pair, or continue without disabling the selected electrode.

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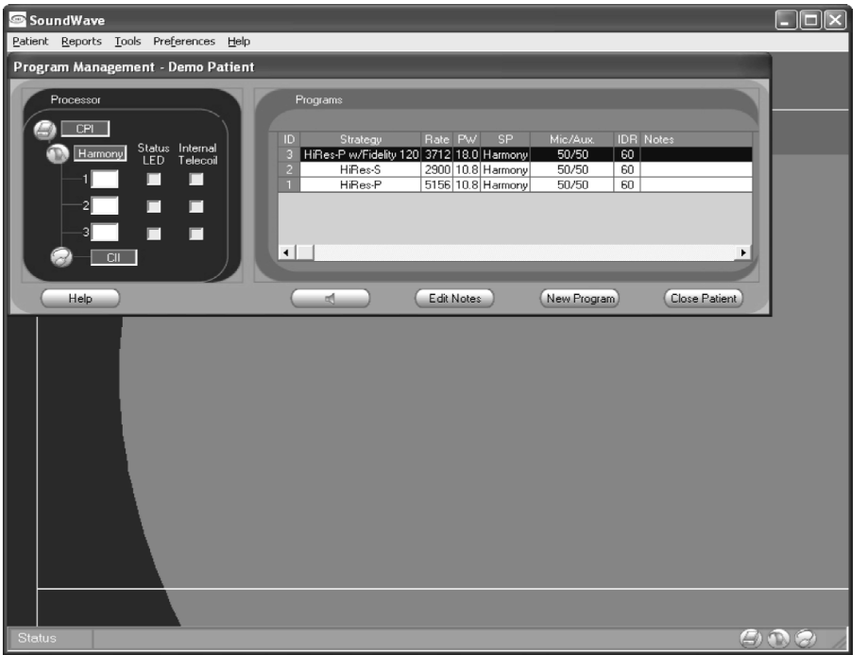
Downloading Programs to Sound Processor

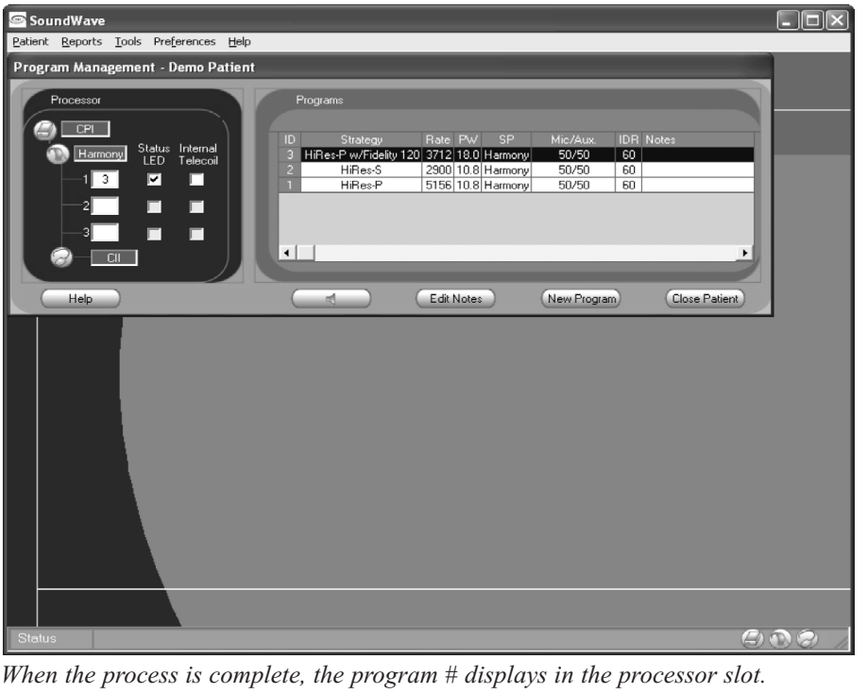
1. From the Program Management window, click and hold the mouse button down on the program ID that you want to copy to the processor.



Although SoundWave allows you to initialize at anytime during a fitting session, it will not let you download programs to the processor until you initialize.

SoundWave prompts you to initialize if you have not done so, when you attempt to download programs to the processor.

2. Drag the program to position over the slot in the processor on the left side (processor field) of the Program Management window, then release the mouse button.
The software copies the program to the processor.



When the process is complete, the program # displays in the processor slot.

Status LED (Harmony only) is checked by default when the program is downloaded. All other options must be explicity checked after initial program download to enable them.

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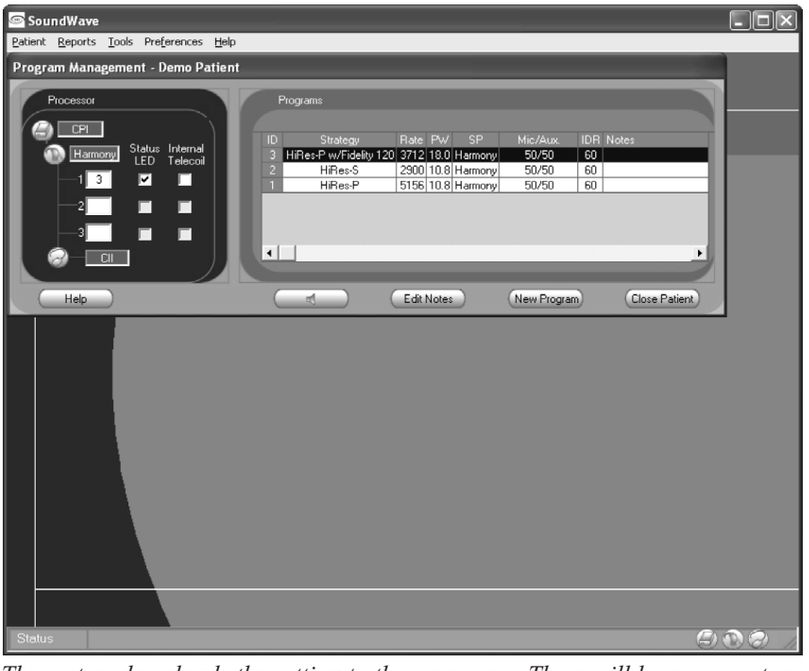
Enabling Alarms (PSP), Status LED, and Internal Telecoil (Harmony)

1. From the Program Management window, click on the checkbox to the right of the program position for the alarm that you want to enable.



The system downloads the setting to the processor. There will be a momentary delay while the setting is written to the processor.

When complete, the system displays a checkmark in the box.

Click the checkbox to the right of the program slots in the Hardware Tree to download the following optional program specific features:

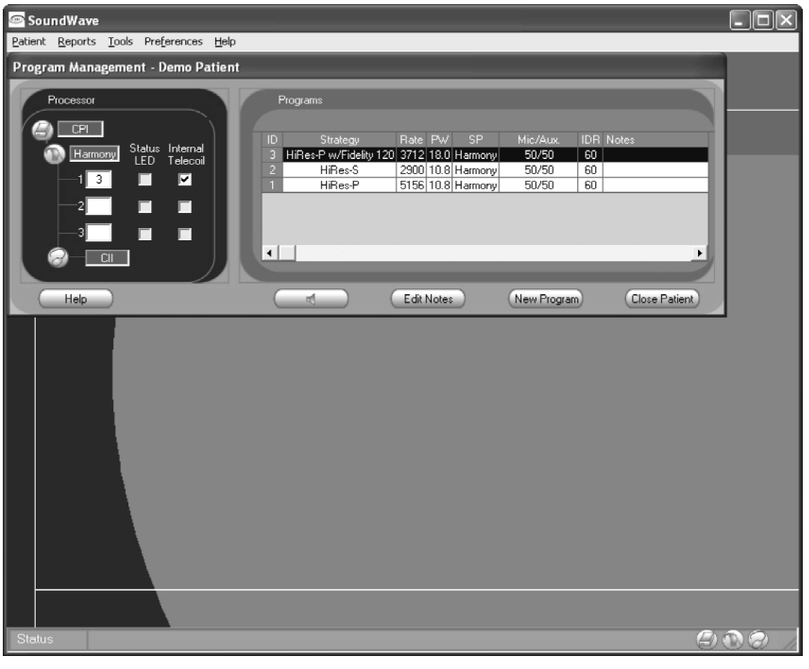
Alarms (PSP only)

Status LED (Harmony only)

Internal Telecoil (Harmony only)

Note: ***You can not enable both Status LED and Internal Telecoil on the same program.***

You must check each option, then wait for the parameter to be downloaded before proceeding to check another option.



Note: ***The Internal Telecoil (Harmony only) capability can only be enabled for programs that have an Auxiliary Audio-mixing ratio set.***

The Internal Telecoil WILL NOT WORK with a program that has Audio-Mixing set to Mic-Only. SoundWave displays a message and will disable the Internal Telecoil option when you download a program with Audio-Mixing set to Mic-Only.

SoundWave will also prevent you from enabling the Internal Telecoil for programs already downloaded to the processor with Audio-Mixing set to Mic-Only.

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Comparing Programs and TalkOver

You can use any program for TalkOver and your patient can compare any programs.

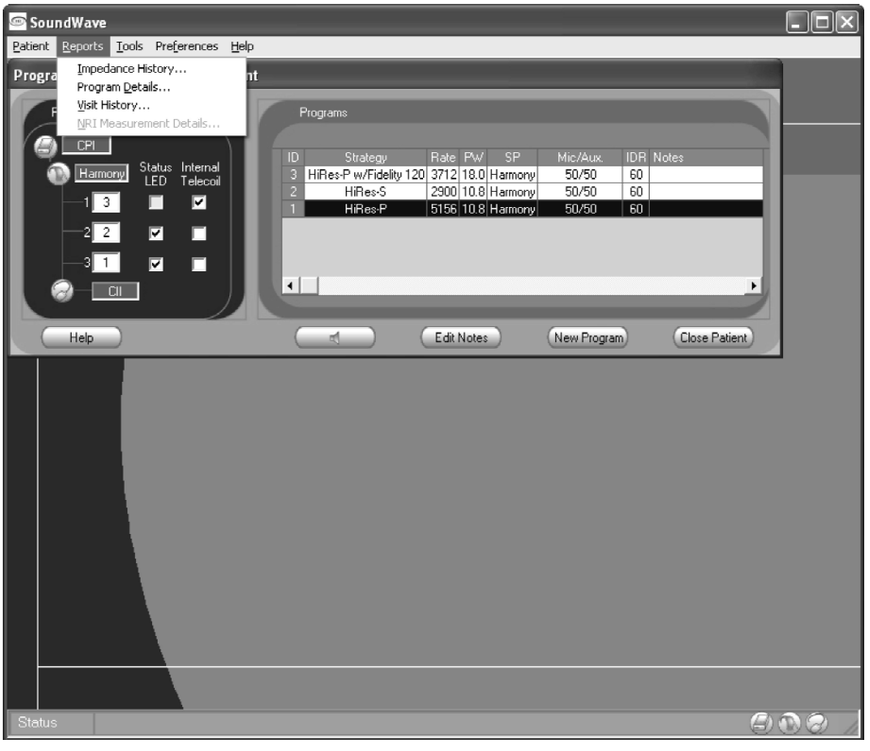
Note: Stimulation is only possible for HiRes with Fidelity 120 programs when connected to a Harmony or PSP processor.

1. Click on any program.
   SoundWave highlights the program.
2. Click on the ***Stimulation*** button.
   The program is active and you can speak to your patient.
3. Click on another program.
   Your patient can compare any programs.

Note: There will be a short silence when changing from one program to another.

Viewing/Printing Reports

You will generate SoundWave reports by accessing the Reports menu. You must have a patient file open to generate a report.



Impedance History Report

Impedances are measured each time you open a patient file with the patient connected (if you have associated the implant with the patient file) and each time you run Electrode Conditioning. You can also manually run impedances. Each time you measure impedances they are saved in the database and stamped with the time and date that they were measured. Impedances can be viewed or printed using the Impedance History Report.

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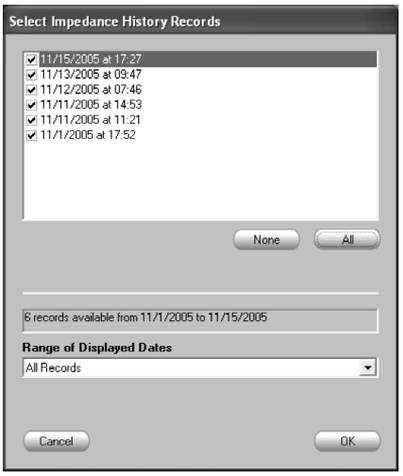
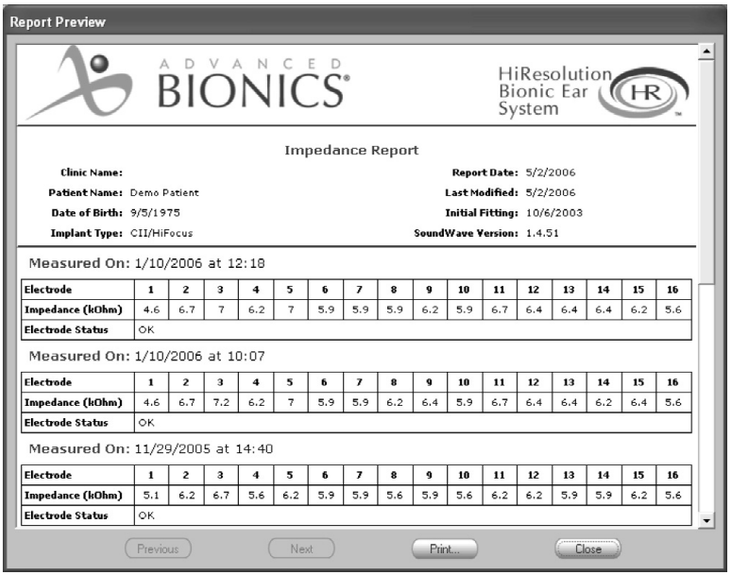
Viewing/Printing an Impedance History Report

1. From the Reports menu, click on the ***Impedance History*** option.
   The software displays the list of impedance records.



2. Select the dates you are interested in, and then click on ***OK***.
   The software displays the report.


Report Preview
ADVANCED BIONICS
HiResolution Bionic Ear System
Impedance Report
Clinic Name:
Report Date: 5/2/2006
Patient Name: Demo Patient
Last Modified: 5/2/2006
Date of Birth: 9/5/1975
Initial Fitting: 10/6/2003
Implant Type: CII/HiFocus
SoundWave Version: 1.4.51
Measured On: 1/10/2006 at 12:18
Electrode 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Impedance (kOhm) 4.6 6.7 7 6.2 7 5.9 5.9 5.9 6.2 5.9 6.7 6.4 6.4 6.4 6.2 5.6
Electrode Status OK
Measured On: 1/10/2006 at 10:07
Electrode 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Impedance (kOhm) 4.6 6.7 7.2 6.2 7 5.9 5.9 6.2 6.4 5.9 6.7 6.4 6.4 6.2 6.4 5.6
Electrode Status OK
Measured On: 11/29/2005 at 14:40
Electrode 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Impedance (kOhm) 5.1 6.2 6.7 5.6 6.2 5.9 5.9 5.6 5.9 5.6 6.2 6.2 5.9 5.9 6.2 5.6
Electrode Status OK
Previous
Next
Print...
Close

3. Click on ***Print*** to send the report to your printer.
4. Click on ***Close*** to close the report window.

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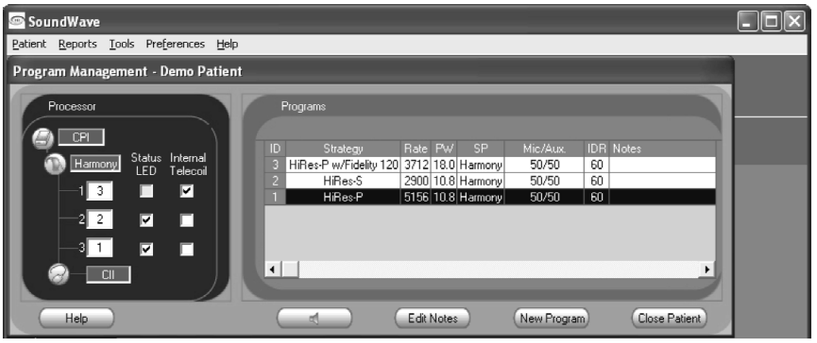
Program Details

SoundWave can generate a report for each patient program. The Program Details report includes all program parameter values.

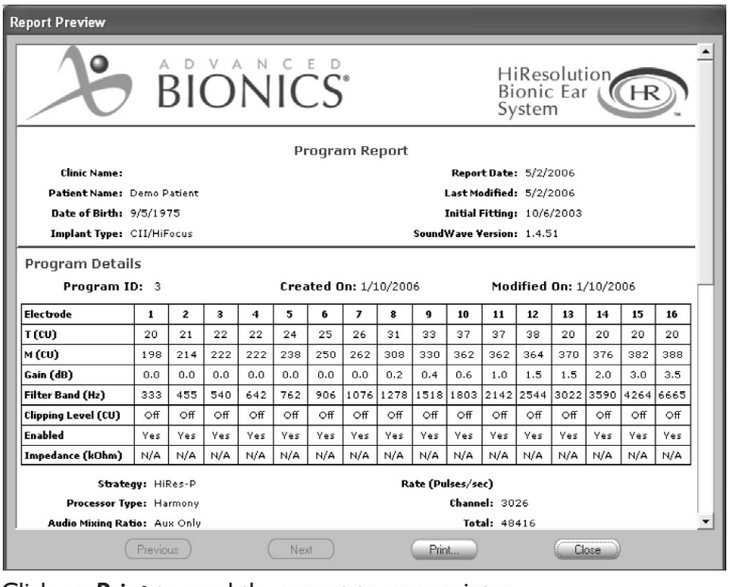
Viewing/Printing a Program Details Report

Note: ***These parameter values are all you will need should you find it necessary to manually re-create a program.***

1. From the Program Management window, click to highlight the program for which you want to generate a report.



2. From the Reports menu, click on the ***Program Details*** option.
   The software displays the program report.


Report Preview
ADVANCED BIONICS
HiResolution Bionic Ear System
Program Report
Clinic Name:
Report Date: 5/2/2006
Patient Name: Demo Patient
Last Modified: 5/2/2006
Date of Birth: 9/5/1975
Initial Fitting: 10/6/2003
Implant Type: CII/HiFocus
SoundWave Version: 1.4.51
Program Details
Program ID: 3
Created On: 1/10/2006
Modified On: 1/10/2006
Electrode 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
T (CU) 20 21 22 22 24 25 26 31 33 37 37 38 20 20 20 20
M (CU) 198 214 222 222 238 250 262 308 330 362 362 364 370 376 382 388
Gain (dB) 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.2 0.4 0.6 1.0 1.5 1.5 2.0 3.0 3.5
Filter Band (Hz) 333 455 540 642 762 906 1076 1278 1518 1803 2142 2544 3022 3590 4264 6665
Clipping Level (CU) Off Off Off Off Off Off Off Off Off Off Off Off Off Off Off Off
Enabled Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes
Impedance (kOhm) N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A
Strategy: HiRes-P
Rate (Pulses/sec)
Processor Type: Harmony
Channel: 3026
Audio Mixing Ratio: Aux Only
Total: 48416
Previous
Next
Print...
Close

3. Click on ***Print*** to send the report to your printer.
4. Click on ***Close*** to close the Report window.

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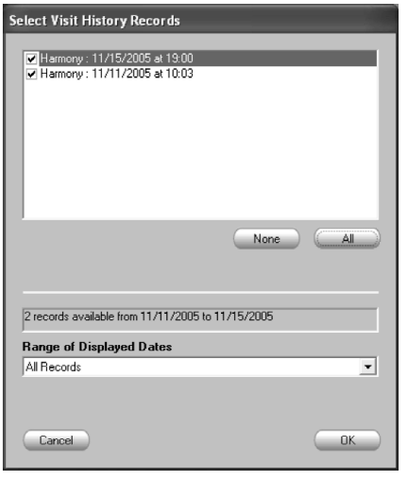
Visit History Report

SoundWave creates a visit history record each time you connect a processor and open a patient file. A visit history record is a "snapshot" of the state of the processor at that moment in time. Only unique visit history records are saved. For example, suppose you create a new patient file at an initial fitting and download programs into each of the 3 processor slots, and then close the patient's file. SoundWave creates and saves a single visit history record detailing the 3 programs and date and time of the download. If you open the patient's file later with the same processor connected and make no changes to the processor (either by downloading programs or changing lock settings), no new visit history record will be created. If you make a change, a new visit history record is created and saved, and available from the Visit History reports option.

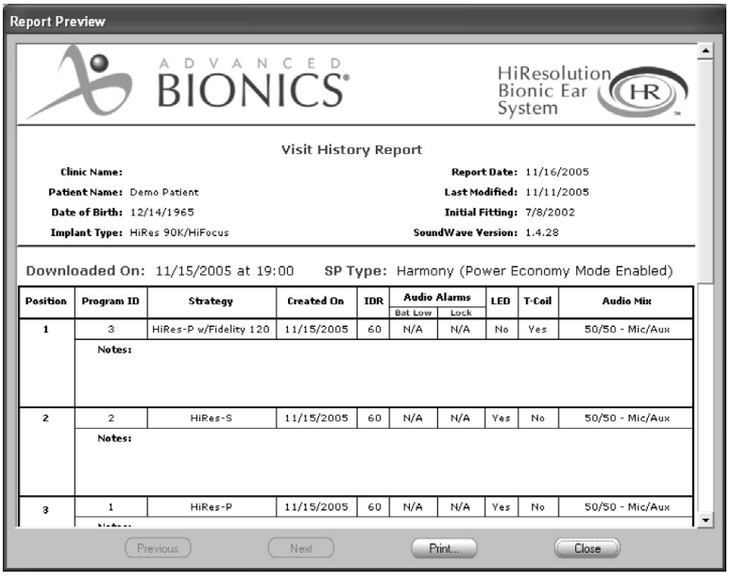
If you connect two patient processors (e.g., a PSP and a BTE) there will be a visit history record generated for each Processor. The Visit History can serve as a communication tool between clinician and recipient/parent/teacher/other by adding notes to each program.

Viewing/Printing a Visit History Report

1. From the Reports menu, click on the ***Visit History*** option.
   The software displays the list of Visit History records identified by the date and time.



2. Select the date(s) you are interested in, and then click on ***OK***.
   The software displays the report.



3. Click on ***Print*** to send the report to your printer.
4. Click on ***Close*** to close the Report window.

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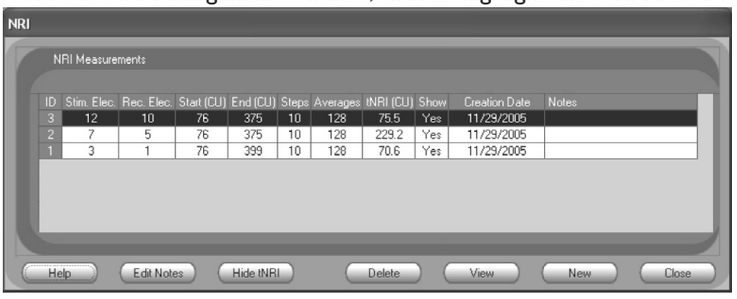
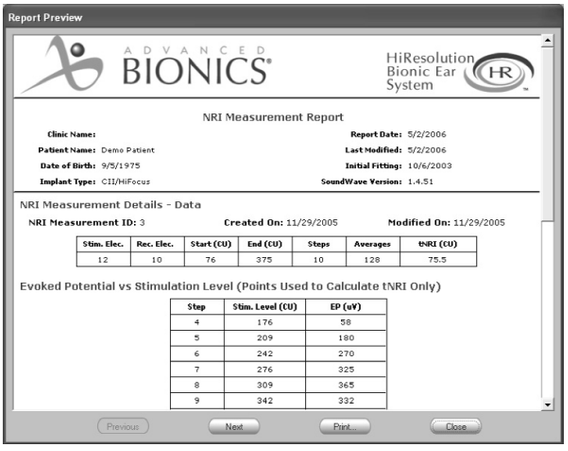
NRI Measurement Details

SoundWave can generate a report detailing data obtained from running the NRI utility. The NRI Measurement Details report includes all values obtained during the measurement. Included in each NRI report is a graphic representation of the waveform.

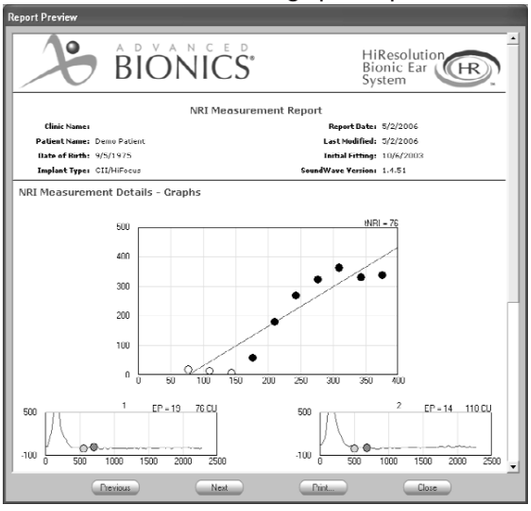
1. From the NRI Management window, click to highlight the NRI record for which you want to generate a report.


NRI
NRI Measurements
ID Stim. Elec. Rec. Elec. Start (CU) End (CU) Steps Averages tNRI (CU) Show Creation Date Notes
3 12 10 76 375 10 128 75.5 Yes 11/29/2005
2 7 5 76 375 10 128 229.2 Yes 11/29/2005
1 3 1 76 399 10 128 70.6 Yes 11/29/2005
Help
Edit Notes
Hide tNRI
Delete
View
New
Close

2. From the Reports menu, click on the NRI Measurements Detail option.
   The software displays the NRI Measurements report.



3. Click on the ***Next*** to see a graphic representation of the I/O function and individual tracings.



4. Click on ***Print*** to send the report to your printer.

5. Click on ***Close*** to close the Report window.

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Managing your Patient Database

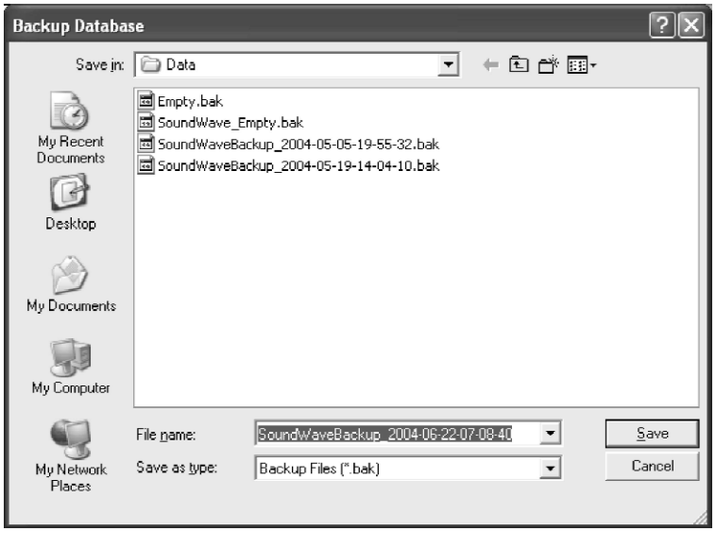
Back Up your Patient Database

Back Up is the process you will use when you want to make a copy of ALL patient files that exist in your patient database. When you back up your database, SoundWave creates a single back up file that contains all of the patient files that make up your database. Backing up on a regular basis is critical to ensure the safety of your patient data. We recommend backing up a minimum of once a week.

Once you have created a backup file you can use it to restore all your patient data should a problem arise with your computer or the SoundWave database. Restoring a database overwrites the entire database with the contents of the back up file.
If you want to combine databases from two or more different computers, do not use the backup and restore process. You will use the export and import processes to merge patients from different databases into a single database.

Backing up your Patient Database

1. Close the patient file if open, you cannot back up when a patient file is open.
2. From the Patient menu, click on Backup Database.
   The system displays the Backup Database dialog box. SoundWave gives the back up file a default name (e.g., SoundWaveBackup_2004-05-07-08-31-26) and includes the date and time. You can accept the default name or type in a name that you prefer.



3. Click on the ***Save In*** menu, and select the ***Desktop*** option.
4. Click on the ***Save*** button.
   SoundWave backs up the file to your desktop.
5. Copy this file to a CD or other removable media.

Note: If you want to back up to a network drive, we recommend first backing up to the Desktop, and then copying to the network drive.

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Export a Patient File(s)

Export is the process that you will use when you want to make a copy of one or more of the patient files that exists in your database. SoundWave allows you to export one patient file, or you can export multiple patient files in one file. Each time you export, SoundWave creates a single file that contains the patient or patients that you specify to be included in the export file.

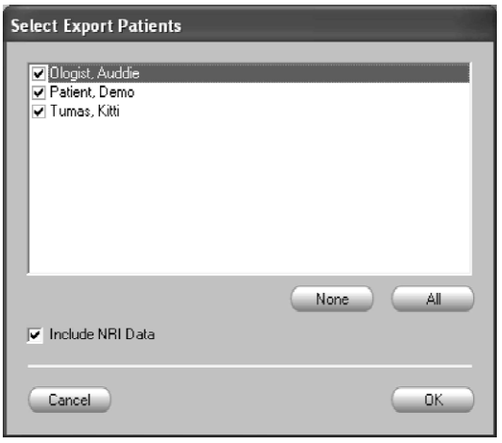
Including NRI

Patient files that include NRI measurements can become very large and you may be unable to export a single patient file to a floppy diskette. You can decrease the size of your patient's file by unchecking the ***Include NRI*** checkbox during the export process, or by deleting unwanted NRI measurements. Remember, once you delete an NRI measurement it is permanently deleted.

Note: ***You will use the export/import feature if you want to merge a patient file(s) that has been programmed on more than one computer or to combine entire patient databases from different computers.***

Exporting a Patient File(s)

1. Close the patient file (if open); you cannot export when a patient file is open.
2. From the File menu, click on ***Export Patients***.
   The system displays the Select Export Patients dialog box. It is here that you can select the patient(s) whose file(s) you want to export. SoundWave selects all patients by default.



3. Click on the box to the left of a patient's name to remove or insert a checkmark.
   A check mark indicates that that patient will be included in the exported file.
4. Click on ***OK***.
   The system displays the Select Export Patients dialog box. SoundWave gives the export file a default name (e.g., SoundWaveExport_2004-05-07-08-31-26) and includes the date and time. You can accept the default name or type in a name that you prefer.
5. Click on the ***Save In*** menu, and select the ***Desktop*** option.
6. Click on the ***Save*** button to initiate the export process.
   SoundWave exports the file to your desktop.
7. Copy this file to a CD or other removable media.

Note: ***If you want to export to a network drive, we recommend first exporting to the Desktop, and then copying to the network drive.***

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Import a Patient File

Import allows you to import one or more patient files into SoundWave's database. You will use the import process to merge databases from two different computers or to add or merge patient files from different databases.

Including NRI

SoundWave will ask you at the beginning of the import process if you want to include the NRI data when you import. This choice applies to all patient files that are to be imported.

Yes	NRI data is imported
No	No NRI data is imported
Cancel	Cancels the import process

Checking for Duplicate Patients

Next, SoundWave will check to see if that patient is already part of your database, and if so will ask you whether you want to merge or skip that patient file. SoundWave will only display a prompt for existing patients, any new patient contained in the file that you are importing are automatically added to your database, and no prompt is necessary.

Yes	Patient data is imported
No	Patient data is skipped
Cancel	Cancels the import process

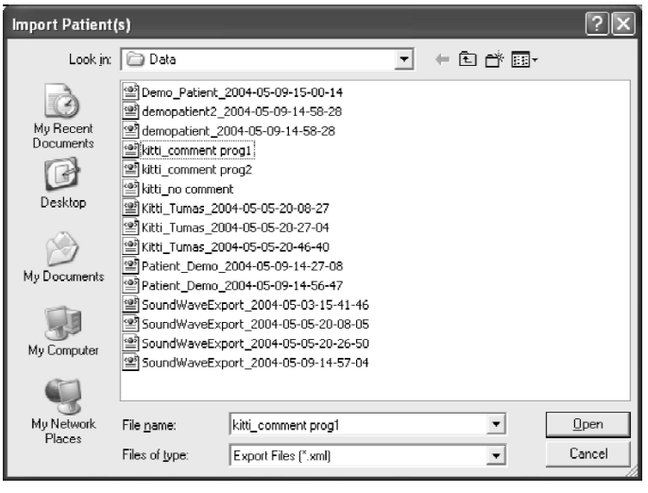
How SoundWave Merges Patient Files

If SoundWave finds that the patient you are trying to import already exists in the database, it will "merge" the two files. SoundWave will import any new patient programs. When the import process is complete, your patient file will include all programs contained in each of the patient files.

Some data however, cannot be merged. This includes data that has been changed or edited such as program notes, patient information (i.e., name, birth date, etc.) and NRI measurements (i.e., NRI notes or N1, P2 point selection), SoundWave looks at these data to determine which are the most recent and retains that data. For example, if you have made changes to program notes that exist in a program from both the file to which you are importing and the file from which you are importing, SoundWave keeps only those notes that were last saved.

Importing a Patient File

1. Close the patient file (if open); you cannot import when a patient file is open.
2. From the Patient menu, click on ***Import Patients***.
   The system displays the Import Patient(s) dialog box.



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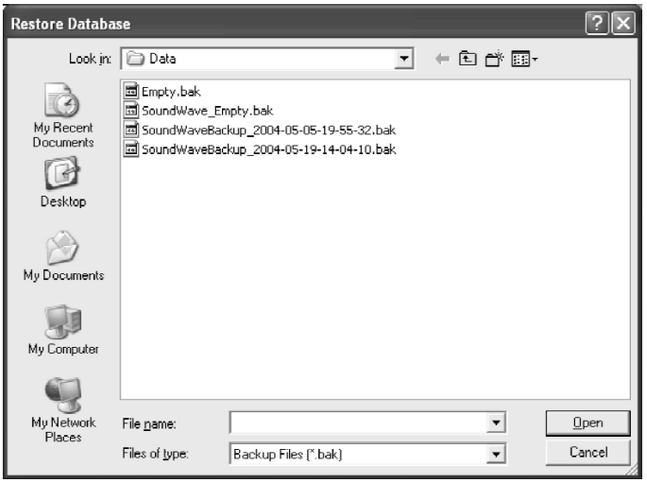
3. Use the ***Look in*** field to browse to the export file location.
4. Click on the patient(s) file.
5. Click on the ***Open*** button to initiate the import process.
   The system closes the dialog box and begins the import process.

   SoundWave will prompt you when necessary to ensure that you wish to merge data for any patient that it finds in the database that is also found in the file from which you are importing.

Restore your Patient Database

Note: You must restore from your hard drive.

1. Locate file to your hard drive and note the location.
2. Launch SoundWave, or if already running with a patient file open, close the patient file.
3. From the Patient menu, click on the ***Restore Database*** option.
   The system displays the Restore Database dialog box.



4. Use the ***Look in*** field to browse to the backup file location.
5. Click on the backup file's name.
6. Click on the ***Open*** button to initiate the restore process.
   The software asks you if you want to overwrite the existing database.

CAUTION: CLICKING ON OK WILL CAUSE THE SOFTWARE TO COMPLETELY OVERWRITE YOUR DATABASE WITH THE ONE YOU HAVE SELECTED. USE CARE TO VERIFY YOU ARE USING THE CORRECT DATABASE.

7. Click on the ***OK*** button.
   The system proceeds with the restore process, overwriting the current database, and closes the dialog box.

Uploading a Patient File from a Sound Processor

Note: You can only import a patient file from a sound processor if the patient does NOT exist in your patient database.

1. With the Main window and Select Patient window open, attach the patient's equipment to your fitting station as usual.
2. Turn on the sound processor.
   SoundWave reads the patient name from the processor and displays it in the menu in the Select Patient window.
3. Click on ***OK***.
   The system adds the patient to the database, measures impedances and displays the Program Management window for that patient.

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Programming CIS or MPS

You can emulate a CIS or MPS strategy type by reducing the number of electrodes, using wider pulse widths and slower rates.

To emulate an MPS or CIS program:

1. Select HiRes-P strategy to emulate an MPS strategy;
   Select HiRes-S to emulate a CIS strategy.
2. Disable every other electrode (Typically use the Odds)
3. Click on Options, and then manually set Pulse Width to 75 uS.

Note: ***This disables Automatic Pulse Width (APW).***

4. Program M levels with Speech Bursts or in Live Speech.
   Program T levels manually (Click on Options, and then click on Manually Set Ts.)
5. Save Program.

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SOUNDWAVE™

PROFESSIONAL SUITE

Neural Response Imaging (NRI)

HARMONY™

HiResolution Bionic Ear System

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Neural Response Imaging (NRI)

Within the SoundWave Professional Suite programming software is a Neural Response Imaging tool. Neural Response Imaging (NRI) is the method by which we can measure responses from the auditory nerve using the HiResolution Bionic Ear System. Using the system's telemetry, one electrode is used to stimulate surviving nerve fibers, while another electrode is used to measure the resulting electrical activity. The ability to measure neural responses is highly dependent upon how much neural tissue remains, the stimulus used, and the recording technique. A neural response is a small change in voltage that occurs when neurons fire in synchrony. NRI is intended to provide a clinically applicable tool used either intra-operatively or postoperatively. NRI can assist the clinician by providing a general indication of program levels, confirmation of neural function, and an assessment of device functionality.

NRI permits the clinician to record the Electrically-evoked Compound Action Potential (ECAP). Stimulation delivered to one of the 16 electrode contacts permits simultaneous recording of the neural response using any of the remaining 15 contacts.

What Are We Measuring With NRI?

In a normal ear, a single auditory nerve fiber generates an action potential when the cell's membrane is depolarized to a threshold value, after which a spike occurs and an action potential is generated. It is possible to measure the electrical activity of neurons using electrodes placed outside of the cells. However, these relatively large electrodes can measure only the voltages that represent the complex sum of spike activity across a large number of nerve fibers. The summed responses of many fibers are termed the compound action potential or CAP. When the response is elicited via electrical stimulation it is referred to as an ECAP. The CAP is also known as Wave I of the auditory brainstem response (ABR).

In order to have enough voltage to measure a CAP, the measuring electrode must be fairly close to the nerve tissue, a sufficient number of neurons must be firing, and the spikes must occur closely in time. Thus, the ability to measure a CAP is highly influenced by how many nerve fibers are available to respond, whether those fibers fire synchronously or are in refractory periods, and the fibers' location with respect to the measuring electrode.

What Does the Electrical CAP Look Like?

A typical electrically elicited CAP (ECAP) consists of a triphasic waveform with a small positive peak (P1) followed by a negative trough (N1) followed by a positive peak (P2). The latency of the CAP, the time between stimulus onset and the onset of P1, is about 250-500 uS. The amplitude of the ECAP is defined as the absolute difference (in uVolts) between N1 and P2. This amplitude usually increases with the magnitude of the stimulating current because more nerve fibers are contributing to the response as the stimulus level is increased.

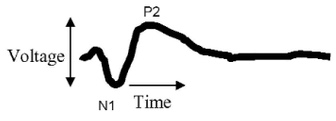

Figure 22: NRI Response (N1 and P2)

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How Does NRI Elicit and Measure the ECAP?

Using the system's telemetry, NRI permits the clinician to record the Electrically-evoked Compound Action Potential (ECAP). Stimulation delivered to one of the 16 electrodes permits simultaneous recording of the neural response using any of the remaining 15 electrodes. The ability to measure the CAP is highly dependent upon how much neural tissue remains, the stimulus used, and the recording technique. Like ABR, CAP amplitudes are so small that they need to be averaged over multiple measurements and require specific parameter settings for recording the response.

Stimulus Waveform

The NRI software uses biphasic pulses to elicit the ECAP (pulsatile stimulation like that used in HiResolution programs). The rise of the pulse must be short enough to produce a synchronous neural response and the pulse width must be shorter than the latency of the response (250-500 uS). In SoundWave NRI, a pulse width of 32 uS in duration is utilized.

Stimulus Rate

The stimulation rate must also be set to allow for synchronous neural firing. With NRI, a stimulation rate of 30Hz is utilized. As stimulation rate increases, nerve fibers will enter their refractory periods. Consequently, the neurons will fire less synchronously and the ECAP will be much smaller or not measurable at all. Therefore, slower stimulations are desirable for measuring CAP responses.

Artifact Cancellation

The typical neural response is rather small in amplitude and is measured in uV. However, one of the technical problems associated with measuring CAPs or ECAPs is that the stimulus artifact is much bigger than—and overlaps—the responses that you want to measure. There are a number of methods to extract the small neural response from the much larger stimulus artifact. The most straightforward and simplest method is the Alternating Polarity (AP) paradigm typically used for ABR recordings.

The HiResolution Bionic Ear System contains a sophisticated internal amplifier that permits an AP paradigm to be used for artifact cancellation. In NRI, inverting the stimulus polarity causes the artifact to invert but not the neural response. When the responses to many stimulus presentations are averaged, the stimulus artifact cancels out (because the alternating positive and negative pulses sum to zero) and the ECAP responses are enhanced. Therefore response to pulses alternating between anodic phase first and cathodic phase first can be used to extract the ECAP.

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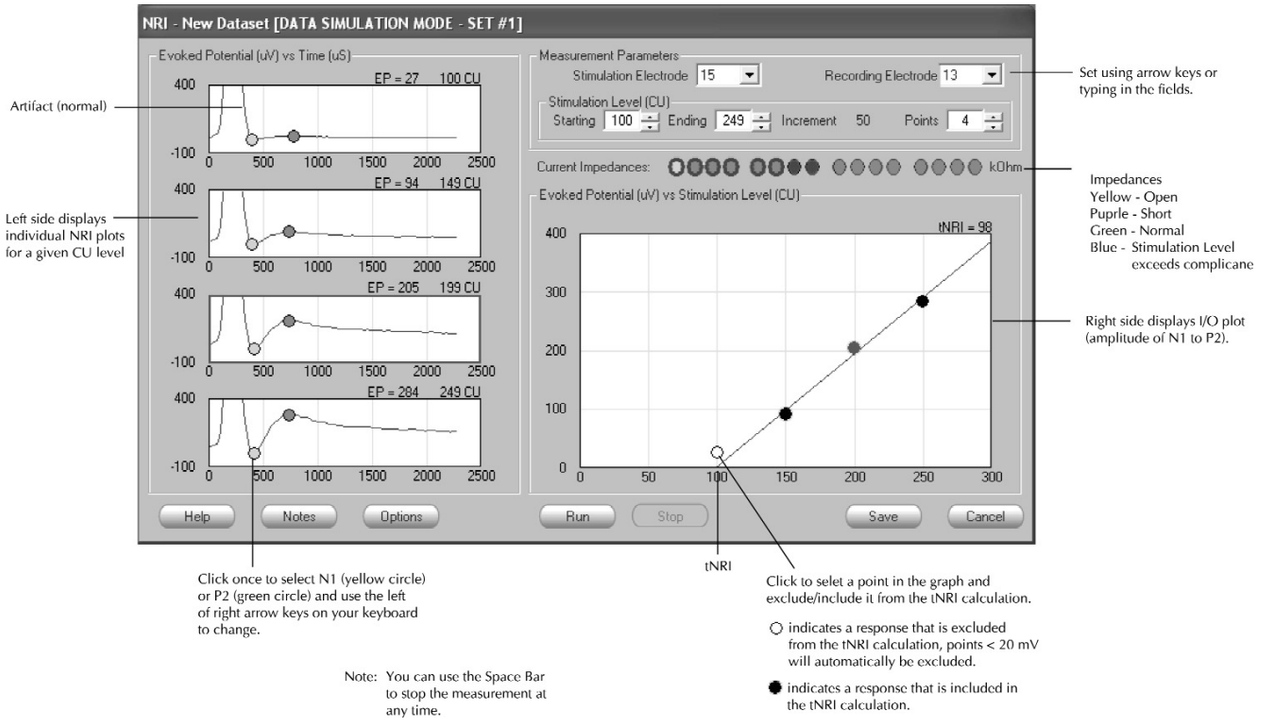
NRI Recording Window

The NRI Recording window is divided into three (3) panes: Measurement Parameters, Evoked Potential (uV) vs Time (uS) and Evoked Potential (uV) vs Stimulation Level (CU). The left side of the window (Evoked Potential (uV) vs Time (uS) displays individual NRI plots for a given CU level. The scale of the NRI plots is automatically set based on the largest response in the series. To verify the presence of a response, it may be necessary for you to adjust the scaling. Adjustments can be made during or after measurements are run. The right side of the window allows you to set the measurement parameters and displays the I/O plot (amplitude of N1 to P2) as the measurement is run.


NRI - New Dataset [DATA SIMULATION MODE - SET #1]
Evoked Potential (uV) vs Time (uS)
EP = 27 100 CU
EP = 94 149 CU
EP = 205 199 CU
EP = 284 249 CU
Measurement Parameters
Stimulation Electrode 15
Recording Electrode 13
Stimulation Level (CU)
Starting 100
Ending 249
Increment 50
Points 4
Current Impedances:
kOhm
Evoked Potential (uV) vs Stimulation Level (CU)
tNRI = 98
Help
Notes
Options
Run
Stop
Save
Cancel
Artifact (normal)
Left side displays individual NRI plots for a given CU level
Set using arrow keys or typing in the fields.
Impedances
Yellow - Open
Puprle - Short
Green - Normal
Blue - Stimulation Level exceeds complicane
Right side displays I/O plot (amplitude of N1 to P2).
Click once to select N1 (yellow circle) or P2 (green circle) and use the left of right arrow keys on your keyboard to change.
tNRI
Click to selet a point in the graph and exclude/include it from the tNRI calculation.
indicates a response that is excluded from the tNRI calculation, points < 20 mV will automatically be excluded.
indicates a response that is included in the tNRI calculation.
Note: You can use the Space Bar to stop the measurement at any time.

Measurement Parameters

Stimulation Electrode

You can use any of the 16 active contacts to stimulate during NRI. Do not select contacts that are not in the cochlea or have out of range impedances (<1 kΩ or >30 KΩ) or shorts.

Recording Electrode

NRI defaults the recording electrode to 2 apical of the stimulation electrode (when electrode 1 or 2 is selected it defaults to 2 basal). Typically the largest responses are recorded on the +2 neighboring electrodes of the stimulating electrode. You can change the recording electrode if needed. The software does not permit you to record and stimulate from the same electrode. Do not select contacts that are not in the cochlea or have out of range impedances (<1 kΩ or >30 KΩ) or shorts.

Stimulation Levels

Starting Stimulation Level (CU)

You can enter a starting level for stimulation in CU, the same units used in HiRes programs to represent charge.

Ending Stimulation Level (CU)

You can enter an ending level for stimulation in CU, the same units used in HiRes programs to represent charge.

Note: You can enter starting and ending stimulation levels in an ascending or descending order based on the clinical situation.

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Points

Points refer to the number of stimulation levels to be applied for measuring NRI incrementally from the Starting Stimulation to the Ending Stimulation Level. The greater the number of Points, the smaller the increment size (in CU) between NRI measures. The measured point at each stimulation level is displayed.

Impedances

The most recent impedances for each electrode display each time you open an NRI Recording window.

Impedances are color-coded as follows:

Yellow - Open
Purple - Short
Green - Normal
Blue - Stimulation Level exceeds compliance

Evoked Potential (uV) vs Time (uS)

Displays the ECAP response waveform for a given stimulation level (CU) updated every 16 samples averaged. NRI will automatically select the NI and P2. These values can be edited as desired at anytime.

Evoked Potential (uV) vs Stimulation Level (CU)

During an NRI evaluation, we want to generate an input-output function. That is, we want to stimulate the neurons with different stimulation levels and measure the N1-P2 amplitude (uV) for each. If we plot the resulting amplitudes as a function of stimulus level (CU), we have an input-output curve or neural growth function. NRI automatically plots this function. NRI will plot a regression line through the input-output function and extrapolate down to the x-intercept. That level is referred to as the "tNRI". At least two points are required to fit a regression line and the software is constrained to use only a positive slope and x-intercept. A filled circle indicates a point included in the regression line. Points below 20 uV and points that are manually excluded, as indicated by open circles, are not included in the regression line.

1st NRI and tNRI:

There are two NRI responses used to compare across electrodes or time, or to compare to HiRes program levels. The first is called "1st NRI". The 1st NRI is defined as the lowest CU level that elicits a response having an N1-P2 amplitude between 20 and 50 uVolts. Typically, that amplitude range is the smallest ECAP that you can actually see. The other NRI response is called the "tNRI." The tNRI value is extrapolated from the points on the input-output plot to identify the stimulus level that would elicit a threshold ECAP response. Note that we cannot really measure the true threshold because it falls within the noise floor.

Why Do We Record NRI At Slow Rates and Wider Pulse Widths Than HiRes Programs?

With NRI, the stimulus pulse width is 32 uS and the pulses are delivered at a rate of 30 pulses per second. Clearly, that pulse width is wider than the pulses typically delivered with HiRes, and the stimulation rate is orders of magnitude slower. Why the differences? First, the pulse width is longer because the charge delivered must be large enough to elicit synchronous neural firing. The stimulation rate is much slower because, as the rate increases, nerve fibers will enter their refractory periods. Consequently, the neurons will fire less synchronously and the ECAP will be much smaller or not measurable at all.

Note the difference. We DO want the nerve fibers to fire synchronously in order to elicit a measurable ECAP. Therefore, we use a SLOW stimulation rate. We DO NOT want the fibers to fire synchronously during everyday HiRes use in order to (1) widen the listener's dynamic range and (2) enable neurons to follow temporal information in the signal. Therefore, we use a HIGH stimulation rate with HiRes.

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How Do We Compare NRI Values and HiRes Program Levels?

NRI and HiRes use the same units (CU) in SoundWave. CU in SoundWave represents charge (pulse amplitude X pulse width). The differences in pulse width result in corresponding changes in pulse amplitude in order to maintain constant charge. Therefore, CU levels can directly be compared between NRI and HiRes programs.

NRI Recording Window Buttons

The following table describes the functions of the buttons located across the bottom of the NRI Recording window.

Table 14: NRI Recording Window Button Description

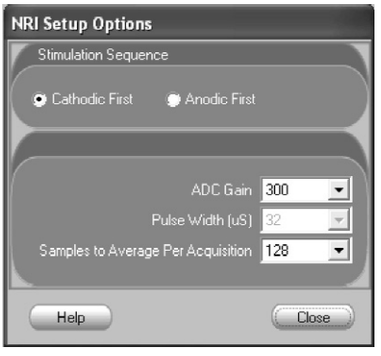
Button	Description
Run	Initiates the recording.
Edit	Available when you open a saved NRI recording. You will be unable to run NRI until you click on the Edit button. Previous tracings are removed, but the parameters remain as set.
Stop	Ends the recording.
Save	Saves the NRI recording to the database. The recording is available from the NRI management window.
Cancel	Closes the window without saving any of the tracings or parameter changes that have occurred.
Options	Displays the NRI Setup options. See the Options section that follows.
Notes	Displays the NRI Notes window. Allows you to enter notes that will be saved with the NRI recording. These notes will print on the NRI Measurement Details report.
Help	Displays context sensitive help for the NRI Recording window.

NRI Options

Clicking on the Options button in the NRI window brings up the following user-settable options.

Stimulation Sequence

You can change which phase presents first, Cathodic or Anodic. The default is Cathodic.



Other Variables That You Can Modify

ADC Gain

ADC Stands for Analog to Digital Converter. The choices for this option are 300 or 1000. The default is 300.

Pulse Width

The default is 32 uS; this option cannot be adjusted by the user.

Samples to Average

By default, NRI will measure and average the responses to 128 stimulus presentations. You can change the number of averages (16, 32, 64, 128 or 256). Increasing the number of samples to average will reduce the noise floor and increase the analysis run time.

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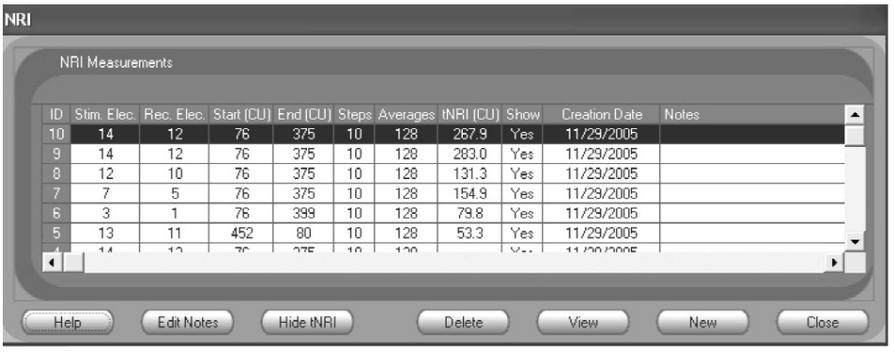
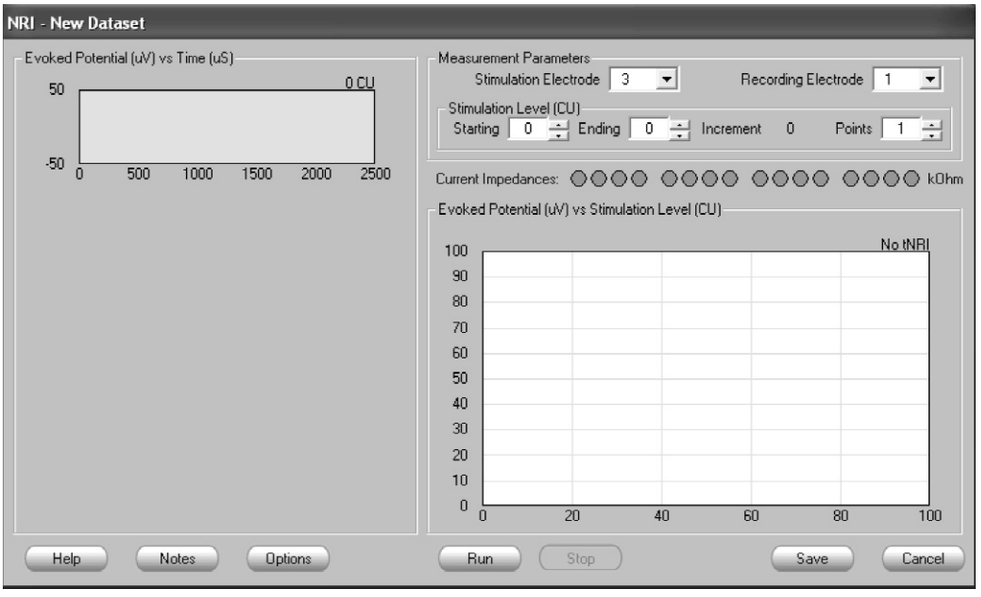
Using SoundWave's NRI tool

1. From an open patient file, click on the NRI option from the Tools menu.
   SoundWave displays the NRI Record Management window.



2. Click on the ***New*** button.
   SoundWave displays the NRI Recording window.



3. Select Stimulating Electrode.
   NRI will by default set the recording electrode 2 apical of the stimulating electrode, except when the stimulation electrode is 1 or 2.
4. Set Starting Stimulation Level in CU.
5. Set Ending Stimulation Level in CU.

Note: You can set starting and ending stimulation levels in an ascending or descending paradigm.

6. Set the number of Points
   You must select >2 points for tNRI. Typically we recommend 6 points. The greater the number of points, the smaller the increment step size.
7. Click on the ***Run*** button to initiate the measurement.

Note: You can use the Space Bar on the keyboard to stop the measurement at anytime.

8. Adjust N1 and P2 if desired.
9. Click on the ***Save*** button to save the data and the NRI Measurement Parameters.

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Entering Starting or Ending Levels

You can enter starting or ending levels by clicking on the up and down arrows to the right of each value; you can also enter levels using number keys on your keyboard. If you type in a level that exceeds the maximum level, SoundWave displays the following message, and then reverts the value back to the previous level.

If you enter a level that is not an allowed level, but that does not exceed the maximum level SoundWave will round the value to the nearest allowable level.

Selecting a Tracing

1. Click once on the tracing field.
   The system highlights the outline of the box in red. Note that the corresponding point in the I/O plot also displays red.

Modifying a N1 or P2 Value

1. Click once on the yellow circle (N1) or green circle (P2).
   Notice that a red box appears around the NRI tracing and that a single point in the I/O plot also displays red indicating the point in the plot for that tracing.

2. Use the left or right arrow keys to move the selected point.

Changing Scaling

1. Click once on the tracing field.
   The system highlights the outline of the box in red.

2. Use the up or down arrow keys to toggle the scaling of the tracing field.

Excluding a Point from the tNRI Calculation

Note: You can exclude a point during or after the NRI measurement. Before excluding a point check the individual tracing and assess visually whether there is a response.

1. Click once on a point in the I/O graph on the right side of the NRI Measurements window.

Stopping Stimulation or Losing Lock or Headpiece Falls Off During NRI Measurement

This message displays if lock is lost or when stim is stopped during NRI measurement.

SoundWave NRI Trial Stopped
The current NRI Trial was stopped.
Would you like to restart the current trial, skip to the next trial or abort the experiment?
NOTE: If you are continuing with the experiment, stimulation will start immediately following this message.
Retry
Skip Next
Abort

Retry: Repeats the CU level when lock was lost or stim was stopped. Previously measured trials are discarded.

Skip/Next: Starts the measurement at the next increment CU level. Previously measured trials are kept.

Abort: Cancels the remainder of the measurement. Previously measured trials are kept.

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Repeating or Editing a Saved NRI Measurement

Double-click on a row in the NRI Management window to open a saved NRI measurment. When you open a saved measurement you can:

- Adjust N1, P2 or modify the I/O function by excluding or re-including points and re-save the measurement.
- Click on the Edit button and then change measurement parameters or click on Run. When you save the new measurement, it is saved as a new record and given the next sequential ID. It does NOT overwrite the previous measurment.

Changing N1, P2 or excluding a point from the I/O function

This version of SoundWave allows you to open a saved NRI measurement, change N1, P2 or which points from the I/O function are included/excluded and then resave the measurement.

Editing Measurement Parameters to Re-run a Saved Measurement

1. From the NRI Management window, double-click on the measurement that you want to edit.
   SoundWave displays the NRI Data window.
2. Click on the ***Edit*** button.
   SoundWave activates the window for editing.
3. Make the desired changes, and then click on ***Run***.
4. Click on ***Save*** to save the changes in a new record, click on ***Cancel*** to close the window without saving changes.

Deleting an NRI Record

NRI data records can be very large. If you find that you have records that you want to discard permanently, you may delete them.

1. From the NRI Record Management window, click once on the record that you want to delete.
   The system highlights that record.
2. Click on the ***Delete*** button.
   The system displays a message to confirm that you want to delete this record, and warning you that it will be permanently removed.
3. Click on the ***Yes*** button.
   The system removes the record.

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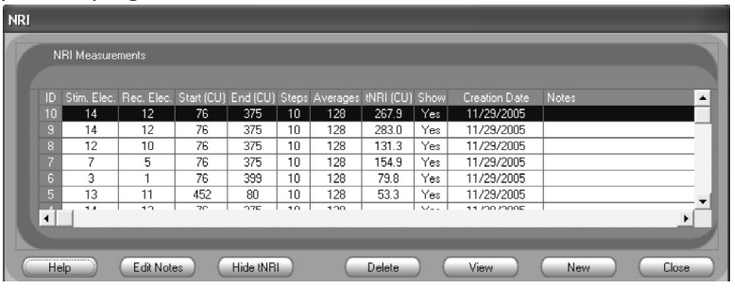
Selecting tNRI to display in the Program Window

SoundWave allows you to display the patient's measured tNRI values in the program window. The setting in the ***Show*** column of the NRI Management window determines whether or not tNRI markers will display in the program window. The setting defaults to "Yes", which indicates that the tNRI value will display in the program window. Changing this setting to "No" precludes tNRI values from displaying in the program window. It is possible that more than one tNRI value may be available from the same electrode. In this case, only the most recent tNRI value for each electrode displays in the program window.

Hiding tNRI levels

You will use this option to prevent the highlighted tNRI value from displaying in the patient's program window.

1. From the NRI Management window, highlight the measurement or row whose values you do NOT want to display in the patient's program window.

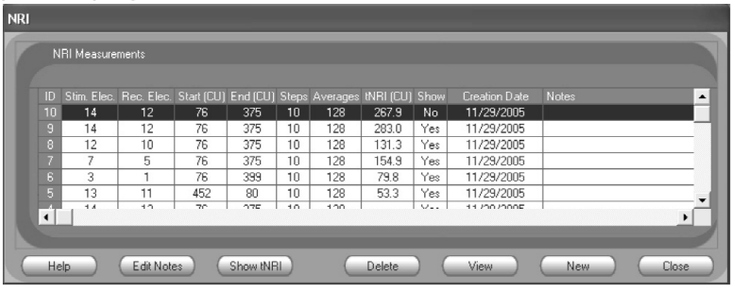


2. Click on the ***Hide tNRI*** button located along the bottom of the window.
   The system displays No in the Show column for the highlighted row and the button label changes to Show tNRI.

Note: ***The Display tNRI option in the Preference menu controls whether the tNRI values that you select here in the the NRI Management window, display on the Program window. This option is enabled by default. If your markers fail to display in the Program window, check to make sure this option is enabled in the Preference menu.***

Showing hidden tNRI levels

1. From the NRI Management window, highlight the row whose value that you want to display in the patient's program window.



2. Click on the ***Show tNRI*** button located along the bottom of the window.
   The system displays Yes in the Show column for the highlighted row and the button label changed to Hide tNRI.

Viewing/Printing NRI Reports

SoundWave can generate a report detailing data obtained from running the NRI utility. The NRI Measurement Details report includes all values obtained during the measurement. Included in each NRI report is a graphic representation of the waveform. See Chapter 2 of this manual for details on viewing/printing an NRI Report.

1. From the NRI Record Management window, click to highlight the NRI record for which you want to generate a report.
2. From the Reports menu, click on the NRI Measurements Detail option.
   The software displays the NRI Measurements report.
3. Click on ***Next*** to see a graphic representation of the I/O function and individual tracings.
4. Click on ***Print*** to send the report to your printer.
5. Click on ***Close*** to close the Report window.

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NRI Recording Guidelines

Step 1: Set NRI Recording Settings

Stimulating Electrode:

- Run on the 3rd electrode of each speech burst band (3,7,11,15).

Recording Electrode:

- Use default (2 apical unless at the end of the array) to start.

Note: Do not use extracochlear contacts or electrodes with out-of-range (open) impedances or shorts for stimulation or recording NRI.

Stimulation Level:

- Set Start Level to behavioral M level (from program) if < 200CU.
- If behavioral M level > 200 CU or not reached by 300CU start at 200CU.
- Set End Level to 50 CU.

Points:

- Set number of points to achieve an increment step size of 10-20 CU.

Averages:

- Use default of 128 averages and use manual averaging.

Note: Use Space Bar to "Abort" CU level once response is observed (no need to complete all 128 averages if not required).

Step 2: Run Measurement

- If a response > 100uV is obtained, verify tNRI calculation from I/O and save.
- If response is not present or is < 100uV, record at increased stimulation level within behavioral comfort limits, but do not exceed compliance limit for an electrode.
  - If you can obtain a neural response with an amplitude >100uV after increasing level, verify tNRI calculation from I/O and save.
  - If you can only measure a neural response <100uV use 1st NRI instead of tNRI from I/O.
  - If you cannot measure a neural response repeat run with a different recording/stimulating electrode.

Creating Programs based on NRI

You can use the following recommendations for creating programs using the data obtained using NRI.

Note: You may initially set M levels at the more conservative 10-20% level below tNRI and then use the volume control to increase loudness or raise Ms while monitoring performance.

If tNRI is <200CU:

Program 1: M levels set to tNRI.

Program 2: M levels set to 20% above tNRI.

Program 3: M levels set to 40% above tNRI.

If tNRI is between 200-300CU:

Program 1: M levels set to tNRI.

Program 2: M levels set to 10% above tNRI.

Program 3: M levels set to 15% above tNRI.

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If tNRI or M levels are >300CU:

Measure ESRT with Speech Bursts.

Program 1: M levels set to 20% below ESRT.

Program 2: M levels set to 10% below ESRT.

Program 3: M levels set to ESRT.

Note: ***For very young children initially select only one strategy.***

Patient may be comfortable with any of these programs, no need to encourage to try each unless progression is necessary for comfort level or based on performance.

Monitor progress with program with objective speech perception measures as well as subjective report.

If Behavioral M level is significantly Higher or Lower than tNRI/ESRT:

Create programs with gradually adjusted M levels (set to level of ESRT or NRI) volume control set -50/0% and monitor performance.

If you cannot measure tNRI or ESRT:

Set M to behavioral levels obtained with Live Speech

If no reliable behavioral measures, contact Advanced Bionics for assistance.

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NRI Measuring Tips

Sound Processor

SoundWave NRI is supported on the PSP and BTE processors. When recording NRI intraoperatively, it is recommended that a PSP be used for convenience and efficiency in a sterile field.

Note: ***There may be insufficient power to measure NRI with an ear level processor, especially with thicker skin flaps and therefore use of a PSP is preferred when administering NRI in such cases.***

Electrode Selection

When selecting electrodes for NRI measurements stimulation or recording, do not use electrodes that meet the following criteria:

- Out-of-range impedances (< 1 kΩ or > 30 kΩ)
- Electrodes that are known to be extra-cochlear
- Shorted or open electrodes
- Electrodes that when stimulated exceed compliance limits

Refer to the color-coded electrode array display to determine electrodes that are:

- Open (yellow)
- Shorted (purple)
- Exceeding Compliance limits (blue circle surrounding green impedance circle)

SoundWave does not prevent the use of these electrodes automatically therefore you need to be aware when you select the electrodes for stimulation and recording to avoid noted Opened and Shorted electrodes. If any electrode elicits a non-auditory sensation, select an apical adjacent contact for NRI measurement.

Note:When setting stimulation levels avoid using levels that cause the blue band to appear around the electrode.

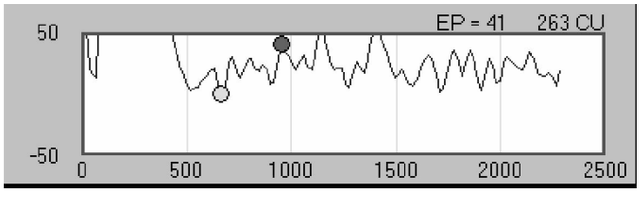
Looking for a Neural Response

The scale of each NRI plot is automatically set based on the largest response in the series. To verify the presence of a response it may be necessary for you to adjust the scaling by clicking on a plot (SoundWave highlights a selected plot in red) and then using the up or down arrow keys to adjust the scale. Adjustments can be made during or after measurements are run.

The I/O Function plots the NRI amplitude against Clinical Unit (CU) level. Typically, the I/O contains a low amplitude noise floor and a linear portion of response growth. Be sure to obtain 4 well spaced points on the linear portion of the I/O function for calculation of tNRI. tNRI is the threshold for the neural response derived by fitting a linear regression line through the I/O function. When response amplitudes are low (<100 uV) and I/O function slope is shallow use 1st NRI (visual) instead of tNRI. 1st NRI is the level that you can first visually detect a neural response with an amplitude of 20-50 uV.

Managing Noise

Responses should be larger than the noise floor. If not, increase number of averages or try another recording electrode (+1 apical or -2 basal).



Verify that the N1-P2 selection is accurate and not within the noise floor. The selection of N1 and P2 will be made within the time window 0-1000 uS. You can monitor the noise floor in the time window beyond 1000 uS. Should the random fluctuations be as large as the amplitude selected for the neural response, you should eliminate that point from the tNRI calculation.

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Manual Averaging

- Use NRI options to set Samples to 256.
- Use the space bar to stop the measurement once a desired response is observed and does not change significantly during an update (no need to gather all 256 samples if not required).
  SoundWave displays the following message.

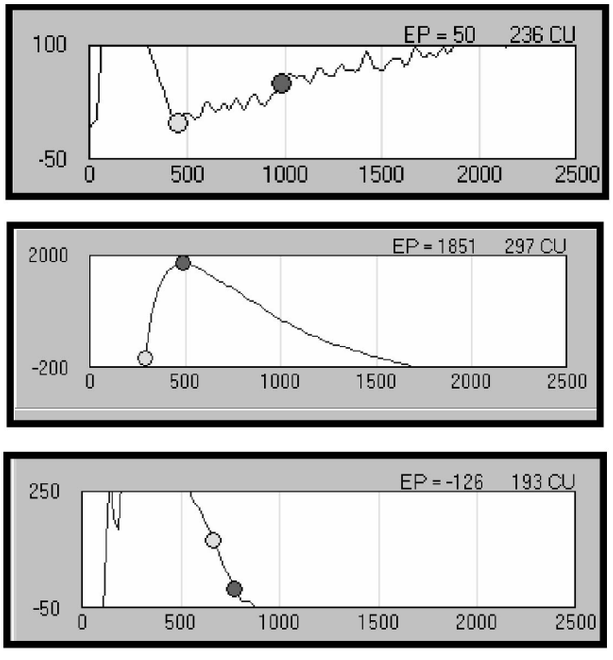
SoundWave NRI Trial Stopped
The current NRI Trial was stopped.
Would you like to restart the current trial, skip to the next trial or abort the experiment?
NOTE: If you are continuing with the experiment, stimulation will start immediately following this message.
Retry
Skip Next
Abort

- Use ***Skip Next*** to continue building an I/O function.
- Use ***Abort if*** you have gathered enough responses and you want to end the measurement

Note: ***This message also displays if lock is lost during NRI measurement.***

Managing Artifact

The following graphic depicts three examples of artifact:
Note atypical response amplitude (too large or negative) typically indicates artifact. Try another recording electrode (+1 apical or -2 basal).



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Using tNRI to Create an Initial Program

1. Obtain tNRI response for at least one electrode.
2. Try obtaining a response in the middle of the array (electrode 8).
3. Set tNRI value as M across the array.
4. Turn down volume control.
5. Set Sensitivity to recommended user setting.
6. Gradually increase volume control in Live Speech to user setting (watch for behavioral response).
7. Globally increase M levels if needed, watching for a behavioral response.

Troubleshooting NRI

If NO behavioral and NO NRI response is obtained try the following:

1. Change the Recording Electrode.
   - Start with the closest neighboring electrode (+1 apical then basal).
2. Increase the number of averages.
3. Increase the maximum stimulation level.
4. Increase by 25 CU at a time (set this new level as both the Starting and Ending Level and set to collect only 1 point).
5. Continue to increase in increments of 25 CU as needed. Do not exceed 600 CU (based on average compliance limit) or exceed compliance limits for stimulation for the selected electrode. Exceeding Compliance limits is indicated by a blue circle that surrounds the green impedance circle on the impedance display.

Note: Be cautious, watch for any behavioral response suggesting stimulation is uncomfortable or loud

6. Change Stimulating Electrode Electrode and Repeat NRI measure on a new electrode.

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SOUNDWAVE™

PROFESSIONAL SUITE

Troubleshooting

HARMONY™

HiResolution Bionic Ear System

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Troubleshooting the HiResolution® Bionic Ear System

A cochlear implant system is sophisticated technology designed to electrically stimulate the impaired auditory system. The auditory system is very complex, but we have an understanding of its responsiveness to electrical stimulation. This chapter provides you with an overview of various situations where an understanding of the equipment and how it interfaces with the auditory system can help you resolve some common patient issues. Some of these suggestions deal with the hardware and others deal with the programming parameters in the software. We hope that the next several pages provide you with a systematic approach for resolving patient issues and the unpredictable hurdles that lie along the path to better hearing.

Keys to Success

Troubleshooting involves investigating and differentiating potential patient or clinician hardware, software and perceptual problems. It is important to keep in mind the following keys to successfully troubleshooting the HiResolution Bionic Ear System:

- Ask good questions.
- Have and use the right tools.
- Practice common sense.

Tools

What are the right tools? The following list details all the tools you will need to properly diagnose problems with the HiResolution Bionic Ear System.

- Spare external hardware or Clinician's Toolbox
- Lights on the PSP and Harmony or FireFly on the Auria
- System Sensor (For use with Platinum/CII BTE, and Auria BTE, not compatible for use with the Harmony BTE)
- Alarms on the PSP
- The patient's description of the problem
- Clinician experience
- Microphone Test Earphones to use the built-in microphone testing function in the PSP or external speaker to test built in Auria and Harmony microphone
- SoundWave HELP files
- Technical Support from Advanced Bionics

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Troubleshooting During Programming in SoundWave

Troubleshooting Clinician Hardware

CPI Not Recognized

1. Is CPI plugged in? Green light on CPI will illuminate if powered.
2. Connect programming cable and processor.
3. Is CPI correctly connected to the COM Port?
   a. Check USB or Serial Port connection. Remove and Reinsert.
   b. Check RS-232 cable connection from CPI to computer.
   c. Check that the appropriate Com Port (Preferences) is selected; Try another com port if needed.
   d. Close and re-start SoundWave.
   e. Reboot computer and re-start SoundWave.

Sound Processor Not Recognized

1. Check that programming Cable plugged in appropriately to CPI.
   a. If using a switch box, verify that it is set to appropriate processor type and connected to CPI.
2. For PSP: Verify that the Program Switch is set to position 1.

   For BTE: Verify that BTE programming cable attached and "locked" in place via the lever.
3. Verify that all the pins on the programming cable are intact.
4. Remove Programming Cable from processor and clean cable pins and processor contact points with alcohol and a hearing-aid brush.
5. Replace Programming Cable.
6. Replace Sound Processor.

Implant Not Recognized (Indicated By Red Icon)

1. Verify that the HP is on the patient's head.
2. Verify correct patient file is open.
3. Check headpiece and cable.

Cannot Measure Impedances or Run Conditioning

This is most frequently seen when programming patients with a skin flap thickness greater than 6-7 mm.

1. If CII BTE or Harmony/Auria is being used:
   a. Use a PSP for impedances and conditioning, and then return to the BTE or Harmony/Auria for HiRes fitting.
   b. If No PSP is available try changing headpiece or BTE. Contact Advanced Bionics. You can continue to program the patient with the ear level processor. SoundWave will utilize defaults impedance values or last recorded impedance values for estimating compliance.
2. Verify that correct Patient File is open and that you have associated the implant with the patient file. The implant icon should be green.

No Sound Heard During Programming in SoundWave

1. Check that the patient's headpiece is on.
2. Check that the volume setting of the processor is at the user setting.
3. Check sensitivity setting on the PSP or setting in software for Harmony/Auria and BTE.
4. Check Status Bar and Hardware tree to verify that all connections are recognized (CPI, SP, and implant).
5. Check that Live Speech is selected and that Stimulation is turned on.

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6. Reassess M levels in Live Speech.
7. Check Audio Mixing ratio.

Troubleshooting Lock

PoEM dynamically adjusts RF as needed to maximize lock stability. PoEM accounts for each patient's unique skin flap thickness, hardware configuration and power needs. If you suspect a lock issue, contact Advanced Bionics for assistance.

Troubleshooting Perceptual Issues during Programming in SoundWave

Tinny Quality or High Frequency Tinnitus or "Ringing"

The perception of ringing may be related to the increased number of electrodes with HiRes programs, the improved fidelity of high frequency information, or the increase rates of stimulation. For many patients, high frequency information was missed with hearing aids or never heard. The reintroduction of high frequencies with electrical stimulation may result in perceptions described like tinnitus. This perception usually dissipates after an adjustment period wearing HiRes.

Evaluate each of the following to reduce the perception of tinnitus or excessive high frequencies, often described as "tinny" or "ringing":

1. Taper off the high frequency gains starting on the last 4 electrodes. Gradually increase high frequency gains over the first week or two of device use, often the issue is resolved.
2. Decrease basal M levels (last 4 electrodes).
3. Set the T level of the last 4 electrodes to 0.
4. Reduce the M level on the last electrode to 0 or set clipping to 0. Gradually increase level over the first few weeks of device use.
5. Disable the most basal electrode (resulting in frequency allocation over the remaining electrodes) in Live Speech.

Echo

Patients may report an echo to Live Speech stimulation. Evaluate the following to reduce the perception of an echo:

1. Try standard instead of extended filters.
2. Try reducing the gain of the apical electrodes (1-3).
3. Try reducing the gain of the basal electrodes (13-16).
4. Try reducing M levels globally.
5. Reduce M levels significantly on the apical (1-3) electrodes. Try reducing electrode 1 by approximately 1/3, and then reduce 2 and 3 slightly less.

Note: ***After the reduction of M levels on the apical three electrodes, patient may report an overall decrease in loudness. Try either globally increasing all M levels or adjusting gains.***

6. Try reducing M levels on basal electrodes (13-16).
7. Create a new program in Live Speech, globally increasing all M levels (flat M) with processor at user settings for volume and sensitivity.
8. Create a program with every other electrode turned off.

Buzz or Hum

1. Try globally reducing your T levels or setting all Ts to 0.
2. If detected during Live Speech (that is globally raising M levels from 0 to M in Live Speech).
   - Patients may report a buzzing sound as you approach or slightly exceed the patient's threshold for electrical stimulation – this is typically resolved by continuing to raise M levels above their threshold.
3. Be certain that the Volume and Sensitivity are at user settings.
4. For Harmony, check that the Internal Telecoil is not enabled.

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Sound is Distant and Unclear

1. When adjusting a program in Live Speech the patient may report an unclear or distant sound quality which is often resolved with continued increases to M levels until comfort is reached.
2. Try globally increasing your T-levels in Live Speech, or adjust T on a electrode-by-electrode basis.
3. Verify that the volume and sensitivity are set appropriately.
4. Try increasing IDR.

Sound is Muffled or Unclear

1. Decrease M levels beginning on first three apical electrodes with each successive electrode contact being deceased slightly less than the former. You may find the need to decrease M levels on electrode 1 up to 1/3 or ½ of the M level.
2. Adjust gains to provide a high freq emphasis/low freq de-emphasis.
3. Increase M levels to see if issue is resolved with additional volume.
4. Double the Pulse Width.
5. Try a different strategy.
6. Create new program with every other electrode turned off.
7. For Harmony, check that the Internal Telecoil is not enabled.

Patient's Voice Is Too Loud

1. Decrease M levels beginning on first three apical electrodes 1, 2 and 3, with each successive electrode contact being deceased slightly less than the former. You may find the need to decrease M levels on electrode contact 1 up to 1/3 or ½ of the M level
2. Adjust IDR.
3. Reduce M levels.

Tonal Quality - Too High Pitched

1. De-emphasize high frequency gains.
2. Recheck patient's M levels on most basal electrodes.
3. Disable most basal electrode(s).

Tonal Quality - Too Low Pitched

1. De-emphasize low frequency gains or apical M levels..
2. Select Standard Filters.

Tonal Quality - Sound Is Hollow

1. Emphasize mid-frequency gains or adjust mid M levels.
2. Ensure that the patient is not hearing an echo from just over-setting M levels, particularly in an open area.

Sound Is Mechanical or "Flutters"

1. Try a different HiRes strategy.
2. Try manually increasing the pulse width in increments of 10.8 uS per phase.
3. Contact Advanced Bionics for programming assistance.

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Unsatisfactory/Distorted Sound Quality

After a patient has been given adequate time to adjust to electrical stimulation, complaints about general dissatisfaction with the sound quality of the implant may persist even after reprogramming and gain adjustments. Single electrode measurements may be warranted at this time:

1. Using tone burst stimulation, adjust M levels for equal loudness using a manual balance across the electrode array disabling any electrode contact(s) that have a significantly higher M level in comparison to the others once all loudness levels have been assessed – adjust to comfort in Live Speech and determine whether program quality is improved.
2. Loudness balance across array using above procedure then complete place-pitch ranking task – remove electrodes demonstrating pitch confusions from program.
3. Decrease M levels beginning on first three apical electrodes with each successive electrode contact being deceased slightly less than the former. You may find the need to decrease M levels on electrode 1 up to 1/3 or ½ of the M level.
4. Create a new program and double the pulse width.
5. Try a different strategy.
6. Create new program with every other electrode turned off.
7. For Harmony, check that the Internal Telecoil is not enabled.

Isolating a Single Electrode Problem

It may be necessary to try to isolate single electrodes that contribute to poor sound quality, FNS or somatic responses using tone burst stimulation.

1. Under Options in SoundWave, (in the Program window) you can select Tone Bursts as opposed to Speech Bursts. Tone bursts are presented on an individual electrode.
2. Tone bursts, at very narrow pulse widths, often require higher stimulation levels to achieve M level. Therefore, troubleshooting with Live Speech is preferred. In cases where tone bursts are required, be cautious and remember to turn down the M levels globally and reduce volume control before returning to Live Speech stimulation.
3. Turn off involved electrodes. Adjust levels as needed and save as a new program.

Facial Nerve Stimulation

Typically, FNS presents during Live Speech stimulation. Therefore in SoundWave, we recommend you begin managing FNS in Live Speech.

Try the following to minimize or eliminate FNS:

1. Attempt to identify and mimic acoustic inputs that elicit FNS in Live Speech, use Display Input to assist in identifying which electrodes have the greatest energy in response to the input.
2. Try clipping the electrodes with the greatest energy noted in Display Input at M level. Try removing the clipping one electrode at a time to isolate electrode specific issues. FNS is often seen on the more basal electrodes, but may be on any electrode or electrodes across the array.
3. For cases of FNS in response to more diverse (or even all) acoustic inputs, globally adjust M levels down to the point below where FNS is elicited – clip at that level then raise M's back to previous level where FNS was observed or reported. Release clipping on one or a few electrode contacts and try to elicit the FNS response – if no FNS continue to release clipping systematically until it is observed or reported – re-clip the electrode contacts involved and continue releasing clipping on the remaining electrode contacts and re-clipping offending electrode contacts until all electrode contacts have been tested – leave all electrode contacts thought to provoke FNS clipped. If the patient reports inadequate loudness adjust input gain to compensate.
4. Turning off a electrode contributing to FNS or a somatic response may be beneficial in some cases. The frequency filter assignments will be automatically reallocated across the remaining electrodes. You may compare the benefits of leaving a electrode in with clipping levels well below M or turning the electrode off.
5. Try a different strategy. Assess both HiRes-P as well as HiRes-S strategies to evaluate FNS presence.

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6. If FNS is elicited before a comfortably loud level of stimulation can be reached, you can disable the auto pulse width algorithm and manually double the pulse width (e.g. if you are currently at 10.8 uS increase to 21.6 uS). Constant charge CUs allow for adjustment in PW without re-measurement of psychophysical levels. Adjust levels as need in Live Speech. If FNS persists, repeat a doubling of pulse width.

Non Auditory Sensations/discomfort

1. Use Tone bursts to assist in identifying involved electrode(s).
2. Use of clipping on associated electrodes.
3. Remove offending electrodes from the program.
4. Assess other strategy types.
5. If the discomfort or non-auditory sensation is chronic or progressive obtain a medical evaluation.
6. Counseling if long-term deafened/congenital adult.

Rapid Adaptation to Stimulation - Patient Requires More Volume Range

Some patients, typically long term deafened individuals, may adapt to HiRes stimulation very quickly, oftentimes during the fitting session, reporting a need for increases in volume control setting above 12:00. To accommodate as much as possible for this phenomenon:

1. Allow the patient to listen to their HiRes program in fitting mode for several minutes prior to downloading to the processor.
2. If possible, provide time for the patient to use HiRes in stand-alone mode for several minutes (30) before leaving the clinic.
3. Download successively louder programs to the processor in case the primary program becomes too soft over time.
4. Set the volume range wide (+100%) to allow for initial adaptation.

Note: ***Levels stabilize within the first few days to weeks of initial stimulation.***

Poor Loudness Growth or High M Levels on Specific Electrodes

1. Some patients, especially long term deafened individuals, may demonstrate poor loudness growth on basal electrode contacts – evaluate this possibility by checking whether Ling sounds are detected for high frequency sounds. If not, increase M levels or disable the most basal electrode contacts until Ling sounds are detected.
2. Disable contacts if M levels are much higher than levels on other electrode contacts and assess perceived sound quality

Note: ***You can use tone bursts to identify individual electrodes with higher level requirements.***

Patients with Previous CIS, MPS or SAS Use before Trying HiRes

A change in sound processing strategy typically involves an adjustment period for most patients. The majority of patients with previous CIS, MPS or SAS use have successfully transitioned and prefer to use HiRes. The adjustment period was reported from as little as a few hours to several weeks. The duration and type of previous strategy does not seem to have a significant impact on a patient's ability to successfully transition to HiRes. Some patients, particularly those doing very well with their CIS, MPS or SAS program, may have greater initial difficulty adjusting to HiRes. The following recommendations apply to patient's transitioning to HiRes from a previous generation strategy.

1. Schedule a fitting appointment at a convenient time conducive to an adjustment period, such as a long weekend, break from school or work, or a holiday.
2. Refrain from immediately "testing" the patient. Limit anxiety by scheduling speech perception testing at later date, once the patient has time to adjust to the new sound processing.
3. Have the patient commit to trying only HiRes for at least 1-2 weeks.
4. Let the patient know that his old program is still available to return if desired or needed after trying HiRes for a suitable time period.
5. Contact Advanced Bionics Clinical Support Team for additional fitting suggestions if needed.

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Troubleshooting Patient Hardware

Hardware related problems often present as a sudden change in sound quality. Most hardware problems are quickly resolved by identifying and changing an involved component. This section describes steps you can take to determine which part of the patient hardware is not functioning properly. In order to troubleshoot, it is important to have spare equipment that is known to be working so that it can be exchanged for expected faulty equipment.

Bionic Toolbox

The Bionic Toolbox contains the necessary tools for testing hardware functionality, troubleshooting issues and dispensing replacement components. The toolbox is divided into two modules (Base Kit and Accessory Kit), which can latch together for ease of storage and carrying.

The Base Kit contains the necessary parts to test patient hardware and assure a successful fitting for all patients no matter which Advanced Bionics device is used. The Accessory Kit includes patient accessories that allow you to replace components for your patients without the delay of ordering a component when it is determined necessary. You can restock and add additional parts to your accessory kit as needed. Our goal is to ensure that you can have patients out the door with hearing, under a variety of presenting circumstances.

The Bionic Toolbox Reference Card (available with the Clinician's Bionic Toolbox kit) is designed to assist clinicians with this troubleshooting.

Sound Processor Microphone Testing

Testing a sound processor's microphone is simple and important. It provides parents, educators and clinicians with the comfort of knowing the microphone is providing sound, or if a microphone needs to be replaced.

How to Test BTE Sound Processor Microphones

To test the microphone of an ear level processor you will need an battery-operated amplified speaker. Hand-held amplified speakers are inexpensive and readily available. For example, Radio Shack® offers a low-cost mini amplified speaker (Audio Amplifier/Speaker, part number 277-1008 at www.Radio Shack.com). You will also need a Direct Connect set or an Auxiliary Audio Earhook and an Audio Interface Cable.

1. Make a note of the programs on the processor. You can also refer to the Visit History for this information.
2. Reinitialize Processor. This deletes all programs from the processor.
3. Designate a program slot for microphone testing. This designated slot can be maintained in the processor for direct patient access to mic testing, if desired.
4. Download patient programs in 2 remaining slots.
5. Remove the processor from the implant user, and ensure it is operating with battery power (do not conduct microphone testing with the processor connected to the fitting system).
6. Set the Program switch to the empty slot position, the slot that you designated for microphone testing.

Note: ***For Harmony Processors only – When the empty program slot is selected, the Harmony Status LED steadily illuminates GREEN for as long as the Program Switch remains in this position. The GREEN LED helps you to identify which slot is empty.***

7. Assemble the Direct Connect set (or BTE aux audio earhook) with the Audio Interface Cable and attach to the processor. For the Harmony, connect the ear/headphones directly into the Direct Connect Cable that is attached to the Direct Connect Earhook and the Harmony Processor, in stand-alone mode powered by a PowerCel.
8. Ensure the amplified speaker is turned off, and plug the audio interface cable into the speaker's audio input port.
9. Keep the processor a full arm's length away from the amplified speaker to avoid feedback. Slowly increase the speaker volume (while at arm's length) while speaking into the processor microphone, until audible. Alternatively, you can plug earphones, including the mic-test earphones, into the external speaker port of the amplified speaker. This reduces the likihood of feedback and eliminates the necessity of holding at arm's length.

Note: ***You will hear feedback or distortion if the processor is too close to the speaker, or if the speaker's volume is too high.***

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How to Test the Platinum Sound Processor (PSP) Microphone:

You will need the Headpiece Microphone Tester Earphones to test the PSP microphone. These earphones are included in each pediatric PSP kit and the Bionic Toolbox. The earphones allow a subjective listening assessment of the quality of the sound as it is received by the headpiece microphone. Intermittencies in the headpiece cable can also be detected.

1. Turn the program switch on the Processor to the microphone tester (Δ) position.
2. Plug the connector of the earphones into the auxiliary jack on the side of the PSP.
3. Place the earphones over your ears to monitor the headpiece microphone and cable.

Frequently Asked Questions:

Q: Does the microphone test assess the cable?
A: It depends on the type of processor. YES, it tests the cable and microphone for the PSP because the microphone is located inside the headpiece. And, NO, it only tests the microphone for ear-level processors.

Q: Why do I hear very loud feedback from the amplified speaker when testing an ear level processor?
A: The processor is placed too close to the speaker, or the volume on the speaker is set too high.

Q: Must the processor system be removed from the patient to test the microphone?
A: Yes. It must be removed.

Q: Can I assess the microphone's sound quality with this test?
A: NO. The quality of sound you hear is dependent on the quality of the amplified speaker you use. The microphone test determines whether or not the microphone is working.

Q: Can I test the T-Mic microphone?
A: NO. The microphone test only assesses the integrated microphone in the ear-level processor.

Q: Do I have to leave the program slot empty to test the microphone?
A: NO for the PSP, which has a designated test position (Δ). YES for ear level processors. You can download a program to the slot after testing the microphone, or you can leave it designated for microphone testing so the parent/caregiver can access this feature independently. Note that the patient will not hear anything if the program control is set to the empty slot. For the Harmony processor, an empty program slot is indicated by the steady green LED display.

Q: Which program slot should I designate for microphone testing with an ear level processor?
A: Whichever program slot you choose. For ease of use, we recommend that you designate the second slot in cases where you want a parent/caregiver to access this feature regularly.

Q: Does the audio mixing ratio setting affect the microphone test for either processor type?
A: NO.

Q: What happens if I test an ear level processor's microphone with a program slot that is loaded with a program?
A: You will hear an intermittent signal from the amplified speaker.

Question Mark Displays in the Hardware Tree Program Slots

This indicates that there is a program on the processor that SoundWave is not able to recognize.

1. Initialize the processor from SoundWave.

Note: ***Initializing will erase the contents of the processor.***

Headpiece Falls Off

1. Increase the magnetic attraction.
2. Shave the hair directly beneath headpiece.
3. Use the PHP clip.
4. Use a headband.
5. Discuss a possible flap revision if necessary.

Note: ***Initial post surgical swelling reduces over time. Monitor change in magnet strength carefully. Routinely check site at each visit.***

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BTE Falls off the Ear

1. Use an Earmold to further secure the BTE to the ear. Ear molds are available for use with a T-Mic, Contact Westone for information about the T-Mic Earmold.
2. Use a Huggie with Auria in the PowerPak configuration.

No Sound Heard During Normal Device Use

1. Auria, CII or Platinum BTE's: Use System Sensor to perform a system functionality check.

Note: ***The System Sensor is not compatible with the Harmony processor. Do NOT use for troubleshooting with Harmony.***

2. Check the battery or PowerCel charge status.
   PSP: Remove and reinsert battery. Check LED light sequence on Processor startup.
   AURIA: Use a FireFly.
   Harmony: Check LED for orange light sequence indicating low or change battery.
3. Try a different, recharged battery or PowerCel.
4. If the problem exists with all the patient batteries or PowerCels, inquire about how long the patient has had the batteries and about the function of the charger.
5. For BTE users: Check the Microphone.
   a. Is a T-Mic being used?
   b. How is the Audio Mixing Ratio set?
   c. For Harmony, check that the Internal Telecoil is not enabled.
   d. Try another T-Mic.
   e. Try a different program position on the processor.

   For PSP Users: Check PHP microphone.
   a. Visually inspect for debris in the microphone port.
   b. Perform a listening check using the mic testing function of the Platinum Sound Processor.
      - Substitute with the auxillary mic. Be aware of the status of the configuration of the Audio Mixing ratio in judging the sound via the auxillary mic.
      - How is the Audio Mixing Ratio set?
6. Try a new headpiece or headpiece cable (see Checking the Headpiece Cable section below).

Note: ***For the Harmony and Auria, the Headpiece and Cable is one unit.***

7. Check patient's sound processor in SoundWave.
   a. Is processor recognized by SoundWave?
   b. Try re-initializing.
   c. Verify that PoEM is selected under options.
   d. Download programs.
8. Try a different processor.

Checking the Headpiece Cable

1. Is the cable properly seated in the jack?
2. Visually inspect for damage to the headpiece cable.
3. Assess for intermittency via the built in microphone testing function on the Platinum Sound Processor.

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Reduction in Battery Life

1. Rule out a problem with a specific battery or PowerCel.
2. Inquire about the age of the batteries or PowerCels and if batteries or PowerCels are rotated.
3. Clean battery or PowerCel contacts and processor contacts.
4. Check if Harmony initialized with Power Economy Mode.
5. Try a HiRes-S program.
6. Contact Advanced Bionics for further assistance if needed.

What to Do If the Sound Processor Gets Wet

1. Turn off the sound processor.
2. Remove the batteries or PowerCels.
3. Shake out water.
4. Place in dry aid kit/carrying case.

Note: Do not try to speed up the drying process

5. Contact center and/or Advanced Bionics.
6. Contact ESCO or insurance agent.

Patient Reports That No Sound Is Heard With Any Audio-Input Accessories

Try one of the following:

1. Check Audio Mixing Ratio. For Harmony, check that the Internal Telecoil is not enabled.
2. Try another assistive listening device.
3. Replace the auxillary microphone, phone adapter or assistive listening device patch cord if applicable; verify attenuation status of the cord.
4. If auxillary mic or phone adapter is functional, check the programmed configuration of the audio-socket to ensure that it has been enabled in software. Check the Audio Mixing ratio setting is appropriately.
5. Perform listening test with battery operated mic tester (if available) to verify internal microphone is working properly.
6. If the patch cord is deemed to be functional, replace the assistive listening device (FM or Infrared System).

Noise

1. Rule out faulty cable and microphone (replace or listening check). Check that the processor volume and/or sensitivity setting is appropriate.
2. Rule out external source of the noise (i.e. patient hearing computer hum, light buzz, etc). For Harmony, check that the Internal Telecoil is not enabled.
3. Counsel the patient that this may disappear with use.
4. Ask the patient to describe the complaint w/o using the word “noise”.
5. Globally reduce the T-levels.
6. Try a narrower IDR (40-50 dB) or decrease T levels globally. Slight adjustments to both IDR and T levels may be necessary to resolve the complaint.
7. Set low-frequency filters to standard.

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8. Does the patient dislike the percept on any particular electrodes? Check single electrode percepts with Tone Bursts, and eliminate electrodes that elicit odd percepts.
9. Replace sound processor.

Distortion

1. Ask the patient how he/she uses the sensitivity control; is it set above 12:00? For Harmony, check that the Internal Telecoil is not enabled.
2. The sensitivity control affects all electrodes equally as it operates on the signal before frequency analysis.
3. Sensitivity control affects the relative level of softer sounds to louder sounds.
4. Think of the function of sensitivity control in terms of changing sensitivity control = shifting the window of acoustic dynamic range.
5. Note that with the sensitivity set to a high level, lower acoustic inputs are placed well within the user's electrical dynamic range. The penalty to the end-user is that signals at normal conversational levels and louder are represented as electrical outputs that may not be very different in amplitude, hence causing some perceptual confusion.
6. On the other hand, setting the sensitivity to a very low level maps cues of normal conversational intensity to electrical levels, which might be far too soft.
7. Test patient in quiet area.
8. Apply gain shaping based upon the patient's description of the distortion.
9. Try deleting electrodes that relate to the patient's description of the distortion (e.g. distortion only occurs on high frequency sounds).
10. Determine if any electrodes are out of balance with Tone Bursts in relation to a neighboring electrode.
11. Disable electrodes with much higher M levels relative to the remaining electrodes.
12. Sweep at M levels with Tone Bursts to determine if the distortion can be detected on any individual electrodes.

Intermittency

1. Check if this occurs with all programs on the processor.
2. Check T-Mic if applicable.
3. Listening check of microphone and cable with microphone testing function of the Platinum Sound Processor or use the battery-powered microphone tester for BTE processors (if available).
4. Check battery or PowerCel.
5. Replace external components one-by-one: headpiece cable, headpiece, sound processor.
6. Verify that PoEM was used for the RF setting.
7. Re-assess RF levels.
8. Contact Advanced Bionics for further assistance.

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Poor Sound Quality

1. Determine whether this is a persistent complaint or a recent change in perceived quality.
2. Rule out external equipment problem.
3. Apply different gain shapes.
4. Change to standard frequency filters.
5. Manipulate IDR.
6. Measure M levels in Tone Bursts.
7. Create completely New Program.
8. Decrease apical M levels significantly.
9. Contact Advanced Bionics for further assistance.

Sound Too Soft At the 12:00 Position or Default Settings

1. Set Speech M using the volume control OR by globally increasing M levels with the volume at 12:00 or the default setting.
2. Re-measure M levels.
3. Adjust gains if needed. Emphasize low and mid frequencies.
4. Ask the patient about his/her listening environments.

Speech Too Loud At the 12:00 Position or Default Settings

1. Globally decrease M levels with volume at 12:00 or default setting.
2. Re-measure M levels.
3. Counsel patient on the difference between the volume and sensitivity controls if applicable.
4. Adjust gain; possibly try de-emphasizing low frequency gain.

Taking Steps to Keep the Processor Working Properly

- Although the system is built to withstand daily wear and tear, a few precautions can be taken to ensure proper functioning.
- Avoid dropping or banging the sound processor.
- Avoid exposing the sound processor and microphone to excessive moisture.
- Avoid exposure to extreme temperatures - below 32° (0° C) to above 115° F (45° C).

Contact info

We have provided you with a Help file in the SoundWave software. This Help file contains detailed programming explanations and demonstrations. We suggest that you review the help file and the tutorials contained in the help file before fitting a patient.

Advanced Bionics has a toll-free customer support number (1-800-261-1961) where support staff may be contacted from 5am to 5pm (PST) to answer questions regarding HiResolution fittings, the SoundWave fitting platform and related hardware, or other technical issues. An additional support number (*877-271-6727) is available for PROGRAMMING CLINICIANS ONLY.*